



06-17-08

AF/3653

Walker
&
Jocke

a legal professional association

Ralph E. Jocke

Patent
&

Trademark Law

June 16, 2008

Mail Stop Appeal Brief - Patents
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Re: **Application No.:** 09/086,857
Confirmation No.: 8855
Appellants: David Frederick, et al.
Title: System For Tracking And Dispensing
Medical Items From Environmentally
Controlled Storage Area
Docket No.: D-1093

Sir:

Please find enclosed the Amended Appeal Brief of Appellants pursuant to 37 C.F.R. § 41.37 for filing in the above-referenced application.

A \$510 fee was already paid for a previously filed Appeal Brief. Thus, no other fee is deemed needed. If necessary, please charge any other fee due to Deposit Account 10-0637.

Very truly yours,

Ralph E. Jocke
Reg. No. 31,029

CERTIFICATE OF MAILING BY EXPRESS MAIL

I hereby certify that this document and the documents indicated as enclosed herewith are being deposited with the U.S. Postal Service as Express Mail Post Office to addressee in an envelope addressed to Mail Stop Appeal Brief - Patents, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 this 16th day of June 2008.

EM 136414320 US
Express Mail Label No.

Ralph E. Jocke

330 • 721 • 0000
MEDINA

330 • 225 • 1669
CLEVELAND

330 • 722 • 6446
FACSIMILE

rej@walkerandjocke.com
E-MAIL

231 South Broadway, Medina, Ohio U.S.A. 44256-2601



D-1093

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

| | | |
|--|---|-------------------|
| Previous Appeal No.: 2005-2434 |) | |
| |) | |
| In re Application of: David Frederick, et al. |) | |
| |) | |
| Application No.: 09/086,857 |) | Art Unit 3653 |
| |) | |
| Confirmation No.: 8855 |) | |
| |) | |
| Filed: May 29, 1998 |) | Patent Examiner: |
| |) | Michael E. Butler |
| Title: System For Tracking And Dispensing |) | |
| Medical Items From Environmentally |) | |
| Controlled Storage Area |) | |

Mail Stop Appeal Brief - Patents
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

**AMENDED APPEAL BRIEF OF APPELLANTS
PURSUANT TO 37 C.F.R. § 41.37**

Sir:

The Appellants hereby submit their Amended Appeal Brief pursuant to 37 C.F.R. § 41.37 concerning the above-referenced Application. This Amended Appeal Brief is in response to the Notice dated May 29, 2008 and the final Office Action dated July 31, 2007.

Comments With Regard To The Remand

The Board of Patent Appeals and Interferences (BPAI) issued a Remand to the Examiner ("Remand") on June 12, 2006. The Remand required the Examiner to correct several issues. As best understood, the Examiner corrected very few (if any) of the issues. For example, cumulative rejections remain pending.

To ease the burden on all involved with this application prosecution, Appellants have already tried to have the Examiner relieved of responsibility for this application prosecution. For example, see the Request dated January 5, 2007. This pending Request has not yet been answered by the Office. The Appellants acknowledge the authority of the BPAI to cause the Examiner to be removed from the prosecution (and require sufficient reason be provided from the examining group for non removal).

Should the BPAI determine that cumulative rejections remain and further Remand is necessary, then Appellants respectfully have a request. Any Examiner-proposed reopening of prosecution resulting from another Remand should be first approved by the BPAI before Appellants are required to respond to such reopening. BPAI approval for a reopening would be based on the reopening not requiring further Remand. It is plainly unfair for Appellants to have to fully respond to further unnecessary cumulative rejections (and other Remand issues) that will later not be considered for review by the BPAI. The USPTO is not permitted to cause Appellants to be stuck in an endless loop of cumulative rejections and BPAI refusal to conduct a review thereof.

(i)

REAL PARTY IN INTEREST

The Assignee of all right, title and interest to the above-referenced Application is
AutoMed Technologies, Inc., a wholly owned subsidiary of AmerisourceBergen Corporation.

(ii) RELATED APPEALS AND INTERFERENCES

A claim 45 rejection may be related to Appeal A992631, as noted in the Advisory Action dated November 7, 2000. Appellants, Appellants' legal representative, and assignee believe that there are no other related appeals or interferences pertaining to this matter.

(iii)

STATUS OF CLAIMS

Claims 1-50 are pending in the Application.

Claims rejected: 1-50

Claims allowed: none

Claims confirmed: none

Claims withdrawn: none

Claim objected to: none

Claims canceled: none

Appellants appeal the rejections of claims 1-50, inclusive. These rejections were in the Office Action ("Action") dated July 17, 2007, which was made final.

(iv)

STATUS OF AMENDMENTS

The Action dated July 31, 2007 was made final. No amendments to the claims were requested to be admitted after the final rejection.

(v) SUMMARY OF CLAIMED SUBJECT MATTER

Concise explanations of exemplary forms of the claimed invention:

For reasons of brevity, claim language may be referred to herein (and in Appellants' arguments) in a shortened version. For example, language such as "at least one" may be simply referred to as "a". Any generalized statement in this Appeal Brief is not to limit any of the mentioned claims in any manner. Please refer to the specific claim for the exact claim language.

With respect to independent claim 1

An exemplary form of the invention is directed to a system for providing medical items (e.g., Specification page 1, lines 2-5; Figures 13 and 40). The system includes a computer (e.g., 84, 300, 324; Figure 55; page 59, lines 12-14) in operative connection with a data store (e.g., 85, 326; page 33, lines 16-17). The data store (e.g., 85, 326) includes user data representative of a plurality of authorized users (e.g., page 33, line 18 to page 34, line 2) and data representative of medical items and their respective storage locations (e.g., page 51, line 18 to page 52, line 3; page 60, line 19 to page 61, line 2).

The system also includes a user interface (e.g., display terminal 76, 98) in operative connection (e.g., LAN 82) with the computer (e.g., 84, 300, 324). The user interface includes an input device (e.g., 78, 80).

The system also includes a refrigerator (e.g., 450), wherein a storage location for at least one medical item is located in an interior area of the refrigerator (e.g., page 57, lines 8-9; page 60, lines 14-16). The refrigerator (e.g., 450) includes a door (e.g., 454). Access to the interior area is controlled by opening and closing the door (e.g., page 61, lines 3-11).

The system also includes a lock module (e.g., 452) operatively attached to the refrigerator (e.g., 450). The lock module (e.g., 452) is in operative connection with the computer (e.g., 84, 300, 324). The lock module (e.g., 452) is operative responsive to a signal from the computer (e.g., 84, 300, 324) to change from a locked condition to an unlocked condition (e.g., page 61, lines 8-11). In the locked condition the refrigerator is prevented from being opened, whereas in the unlocked condition the door is able to be opened (e.g., page 51, lines 8-11).

The system allows a user to input identification data through the input device (e.g., 78, 80) of the interface (e.g., 76, 98) that corresponds to data representative of an authorized user stored in the data store (e.g., 85, 326; page 33, line 18 to page 34, line 2). Responsive to identification input corresponding in the data store to one of the plurality of authorized users, the user can then input medical item indicia through the input device (e.g., 78, 80) (e.g., page 55, lines 10-12). The computer is operative responsive to the medical item indicia input, to output a signal that causes the lock module (e.g., 452) to change to the unlocked condition (e.g., page 55, lines 13-16; page 56, lines 3-8).

With respect to independent claim 24

Another exemplary form of the invention is directed to a system. Support in the disclosure for similar claim language has previously been provided.

The system (e.g., Figures 13 and 40; Specification page 1, lines 2-5) includes a computer (e.g., 84, 300, 324; Figure 55; page 59, lines 12-14) in operative connection with a data store (e.g., 85, 326; page 33, lines 16-17). The data store (e.g., 85, 326) includes user data representative of authorized users (e.g., page 33, line 18 to page 34, lines 2-4) and data

representative of medical items and their respective storage locations (e.g., page 51, line 18 to page 52, line 3).

The system also includes a user interface (e.g., 76, 98) in operative connection (e.g., 82) with the computer (e.g., 84, 300, 324), and the interface includes an input device (e.g., 78, 80).

The system also includes a preexisting housing structure (e.g., refrigerator 450), wherein a storage location for at least one medical item is located in an interior area of the housing structure (e.g., page 57, lines 8-9; page 60, lines 14-16). The housing structure (e.g., 450) includes a door (e.g., 454), and access to the interior area is controlled by opening and closing the door (e.g., page 61, lines 3-11).

The system also includes a lock module (e.g., 452) mounted on an exterior surface of the housing structure (e.g., 450), and the lock module (e.g., 452) is in operative connection with the computer (e.g., 84, 300, 324), and the lock module is operative responsive to a signal from the computer (e.g., 84, 300, 324) to change from a locked condition to an unlocked condition (e.g., page 61, lines 8-11). In the locked condition the door is prevented from being opened, and in the unlocked condition the door is able to be opened (e.g., page 61, lines 9-11).

The system allows a user to input identification data, through the input device (e.g., 78, 80) of the interface (e.g., 76, 98), that corresponds to data representative of an authorized user stored in the data store (e.g., 85, 326) (e.g., page 33, line 18 to page 34, line 2). Responsive to the identification input, the computer (e.g., 84, 300, 324) enables the user to input item indicia corresponding to a medical item through the input device (e.g., page 55, lines 10-12). The computer is operative responsive to the medical item indicia input, to output a signal changing

the lock module (e.g., 452) to the unlocked condition (e.g., page 55, lines 13-16; page 56, lines 3-8).

With respect to independent claim 27

An exemplary form of the invention is directed to a method. Support in the disclosure for similar claim language has previously been provided. The method includes attaching a lock module (e.g., 452) to a refrigerator (e.g., 450), to selectively enable access (e.g., Specification page 57, lines 9-10) to an interior area of the refrigerator (e.g., 450). The method further includes placing a medical item (e.g., page 57, lines 6-9) in the interior area of the refrigerator (e.g., 450). The method provides for storing in a store data (e.g., 85, 326; page 33, lines 16-17), data representative of a type associated with the medical item placed in the interior area (e.g., page 60, line 19 to page 61, line 2). The method also provides for inputting through an input device (e.g., 78, 80), an input corresponding to the type of medical item stored in the interior area (e.g., page 55, lines 9-13). The method additionally provides for determining with a computer (e.g., 84, 300, 324; Figure 55; page 59, lines 12-14) in operative connection (e.g., 82) with the data store (e.g., 85, 326), the lock module (e.g., 452), and the input device (e.g., 78, 80), that the type of medical item corresponding to the input is stored in the interior area (e.g., page 55, lines 9-17). The method also includes generating a signal with the computer (e.g., 84, 300, 324) responsive to the determination that the medical item is stored in the interior area (e.g., page 55, line 15). The method further includes enabling access with the lock module (e.g., 452) to the interior area responsive to the signal (e.g., page 56, lines 10-11). Further description related to the exemplary form of the invention may be found at pages 54-60 and Figures 14, 40, 50-55.

With respect to independent claim 44

Another exemplary form of the invention is directed to a method. Support in the disclosure for similar claim language has previously been provided. The method includes attaching a lock module (e.g., 452) to a housing structure (e.g., refrigerator 450), to selectively enable access (e.g., Specification page 57, lines 9-10) to the interior area of the housing (e.g., 450). The method further includes placing a medical item (e.g., page 57, lines 6-9) in the interior area of the housing (e.g., 450). The method additionally provides for storing in a data store (e.g., 85, 326; page 33, lines 16-17), data representative of a type associated with the medical item placed in the interior area (e.g., page 60, line 19 to page 61, line 2). The method also provides inputting through an input device (e.g., 78, 80), an input corresponding to the type of medical item stored in the interior area (e.g., page 55, lines 9-13). The method further provides for determining with a computer (e.g., 84, 300, 324; Figure 55; page 59, lines 12-14) in operative connection (e.g., 82) with the data store (e.g., 85, 326), the lock module (e.g., 452), and the input device (e.g., 78, 80), that the type of medical item corresponding to the input is stored in the interior area (e.g., page 55, lines 9-17). The method also includes generating a signal with the computer (e.g., 84, 300, 324) responsive to the determination that the medical item is stored in the interior area (e.g., page 55, line 15). The method further includes enabling access to the interior area with the lock module (e.g., 452) responsive to the generated signal (e.g., page 56, lines 10-11). Further description related to the exemplary form of the invention may be found at pages 54-60 and Figures 14, 40, 50-55.

With respect to independent claim 45

Another exemplary form of the invention is directed to a system. Support in the disclosure for similar claim language has previously been provided. The system (e.g., Figures 13 and 40; Specification page 1, lines 2-5) includes a computer (e.g., 84, 300, 324; Figure 55; page 59, lines 12-14) in operative connection (e.g., 82) with a data store (e.g., 85, 326; page 33, lines 16-17). The data store (e.g., 85, 326) includes user data representative of authorized users (e.g., page 33 line 18 to page 34 line 2) and data representative of medical items and their locations (e.g., page 51, line 18 to page 52, line 3; page 60, line 19 to page 61, line 2).

The system also includes a user interface (e.g., 76, 98) in operative connection (e.g., LAN 82) with the computer (e.g., 84, 300, 324), and the interface includes an input device (e.g., 78, 80). The system also includes a housing structure (e.g., 450), wherein a storage location for at least one medical item is located in an interior area of the housing (e.g., 450; page 57, lines 8-9; page 60, lines 14-16). The housing includes a door (e.g., 454), and access to the interior area is controlled by opening and closing the door (e.g., page 61, lines 3-11).

The system also includes a lock (e.g., 452) mounted in operative connection with the housing (e.g., 450), and the lock (e.g., 452) is in operative connection with the computer (e.g., 84, 300, 324). The lock is operative responsive to a signal from the computer (e.g., 84, 300, 324) to change from a locked condition to an unlocked condition (e.g., page 61, lines 8-11). In the locked condition the door is prevented from being opened, and in the unlocked condition the door is able to be opened (e.g., page 61, lines 9-11).

The system allows a user to input identification data through the input device (e.g., 78, 80) of the interface (e.g., 76, 98), which data corresponds to data representative of an authorized

user stored in the data store (e.g., 85, 326; page 33 line 18 to page 34 line 2). Responsive to the input identification, the computer (e.g., 84, 300, 324) enables the user to input item indicia corresponding to a medical item through the input device (e.g., 78, 80; page 55, lines 10-12). The computer is operative responsive to the medical item indicia input to output a signal changing the lock to the unlocked condition (e.g., page 55, lines 13-16; page 56, lines 3-8).

With respect to independent claim 48

Another exemplary form of the invention is directed to a system. Support in the disclosure for similar claim language has previously been provided. The system (e.g., Figures 13 and 40; Specification page 1, lines 2-5) includes a user interface (e.g., 76, 98) with at least one user input device (e.g., 78, 80). The system also includes at least one data store (e.g., 85, 326; page 33, lines 16-17) that stores item data representative of each of a plurality of medical items. The data store (e.g., 85, 326) also stores location data corresponding to each of a plurality of storage locations in which the plurality of medical items are stored (e.g., page 51, line 18 to page 52, line 3; page 60, line 19 to page 61, line 2). The data store (e.g., 85, 326) further stores user identifiers representative of different authorized users (e.g., page 43, lines 5-6 and 16-18; page 55, lines 2-8).

The system also includes at least one computer (e.g., 84, 300, 324; Figure 55; page 59, lines 12-14). The computer is in operative connection (e.g., 82) with the data store (e.g., 85, 326) and the user interface (e.g., 76, 98). The computer (e.g., 84, 300, 324) is operative to determine if data received with the input device (e.g., 78, 80) corresponds in the data store (e.g., 85, 326) to an authorized user (e.g., page 43, lines 5-6 and 16-18). The computer is further operative to

determine whether data received with the user input device (e.g., 78, 80) corresponds in the data store (e.g., 85, 326) to a particular medical item (e.g., page 56, lines 3-8).

The system includes a medical item housing (e.g., 450) that includes a storage location for at least one medical item represented in the data store (e.g., 85, 326; page 57, lines 6-9). The medical item storage location is represented by location data in the data store (e.g., page 56, lines 5-11).

The system also includes a lock (e.g., 452), that selectively controls access to the medical item storage location (e.g., page 57, lines 9-10). The lock (e.g., 452) in a locked condition prevents access to the medical item storage location, and in an unlocked condition permits access to the medical item storage location (e.g., page 60, lines 3-8). The lock (e.g., 452) is further in operative connection with the computer (e.g., 84, 300, 324) and is operative responsive to at least one signal from the computer (e.g., 84, 300, 324) to change from the locked condition to the unlocked condition (e.g., page 57, line 11-16; page 58, lines 8-9).

The computer (e.g., 84, 300, 324), responsive to the user input device (e.g., 78, 80) receiving input that corresponds to a particular user identifier in the data store (e.g., 85, 326), allows input to be received through the user input device (e.g., page 33 line 18 to page 34 line 2) that corresponds to a particular medical item represented in the data store (e.g., page 56, lines 3-8). The computer (e.g., 84, 300, 324) is responsive to the particular medical item input to cause output of the at least one signal (e.g., page 60 lines 3-8) to change the lock (e.g., 452) from the locked condition to the unlocked condition (e.g., page 57, line 11-16; page 58, lines 8-9) to permit access to the particular medical item storage location.

(vi) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

For ease of following the cumulative rejections, the following 24 issues have been chronologically referenced herein as issues #1 to #24.

1. Whether claims 27-43 are unpatentable under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Appellants regard as the invention.
2. Whether claims 1, 3, 9, 24-25, 27, 31-33, 36-38, 42-44 and 48-50 are unpatentable pursuant to 35 U.S.C. § 102(b) as being anticipated by Lavigne, et al. (US 5,572,873) ("Lavigne").
3. Whether claims 1, 4, 12-15, 21, 24, 27-29, 31-33, 39, 41, 44, 48, and 50 are unpatentable pursuant to 35 U.S.C. § 102(b) as being anticipated by Colson, Jr. et al. (US 5,520,450) ("Colson '450").
4. Whether claims 45 and 48-50 are unpatentable pursuant to 35 U.S.C. § 102(b) as being anticipated by Pearson (US 5,562,232).
5. Whether claims 46, 48, and 50 are unpatentable pursuant to 35 U.S.C. § 102(e) as being anticipated by Higham et al. (US 5,805,456) ("Higham").

6. Whether claim 45 is unpatentable pursuant to 35 U.S.C. § 102(b) as anticipated by Colson, Jr. et al. (US 5,346,297) ("Colson '297").
7. Whether claims 2 and 26 are unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Lavigne in view of Nemoto (US 4,237,439), Keskin, et al (US 5,894,277), and Tabata (US 4,656,850).
8. Whether claim 46 is unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Higham.
9. Whether claims 1, 3, 24-26, and 41 are unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Lavigne in view of Aten et al. (US 4,674,652) ("Aten").
10. Whether claims 1-3 and 24-25 are unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Colson '450 in view of Lavigne.
11. Whether claims 45-50 are unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Blechl et al. (US 5,377,864) ("Blechl") in view of Weinberger (US 5,408,443).
12. Whether claims 16-20 and 34-35 are unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Lavigne in view of Engleson et al. (US 5,781,442) ("Engleson").

13. Whether claims 4-8 and 40 are unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Colson '450 in view of Iwamoto et al. (US 5,575,515) ("Iwamoto").
14. Whether claim 23 is unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Colson '450 in view of Warren (US 5,225,825).
15. Whether claims 9, 16-17, 20, 22, and 34-35 are unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Colson '450 in view of Holmes (US 6,039,467).
16. Whether claims 9, 16-17, 20, 22, 34-35, and 42-44 are unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Lavigne in view of Holmes.
17. Whether claims 45 and 48-50 are unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Halvorson (US 4,847,764) in view of McDonald, et al. (US 5,314,243) ("McDonald").
18. Whether claims 45-50 are unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Halvorson in view of Weinberger.
19. Whether claims 16-20 and 34-35 are unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Colson '450 in view of Gombrich et al. (US 4,857,716) ("Gombrich").

20. Whether claims 4-11 and 21 are unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Lavigne in view of Iwamoto.
21. Whether claims 11-15 and 23 are unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Lavigne in view of Genest et al. (US 4,125,008) ("Genest").
22. Whether claim 41 is unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Colson '450 in view of McDonald.
23. Whether claim 41 is unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Colson '450 in view of Weinberger.
24. Whether claims 30 and 41 are unpatentable pursuant to 35 U.S.C. § 103(a) as being unpatentable over Colson '450 in view of Higham.

(vii)

ARGUMENT

The Applicable Legal Standards

Anticipation pursuant to 35 U.S.C. § 102(b) requires that a single prior art reference contain all the elements of the claimed invention arranged in the manner recited in the claim. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983).

Anticipation under 35 U.S.C. § 102(b) requires in a single prior art disclosure, each and every element of the claimed invention arranged in a manner such that the reference would literally infringe the claims at issue if made later in time. *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 USPQ2d 1766, 1768 (Fed. Cir. 1987).

Anticipation by inherency requires that the Patent Office establish that persons skilled in the art would recognize that the missing element is necessarily present in the reference. To establish inherency the Office must prove through citation to prior art that the feature alleged to be inherent is "necessarily present" in a cited reference. Inherency may not be established based on probabilities or possibilities. It is plainly improper to reject a claim on the basis of 35 U.S.C. § 102 based merely on the possibility that a particular prior art disclosure could or might be used or operated in the manner recited in the claim. *In re Robertson*, 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999).

Before a claim may be rejected on the basis of obviousness pursuant to 35 U.S.C. § 103, the Patent Office bears the burden of establishing that all the recited features and relationships of the claim are known in the prior art. This is known as *prima facie* obviousness. To establish *prima facie* obviousness, it must be shown that all the elements and relationships recited in the

claim are known in the prior art. If the Office does not produce a *prima facie* case, then the Appellants are under no obligation to submit evidence of nonobviousness. MPEP § 2142.

The evidence of record must teach or suggest the recited features. An assertion of basic knowledge and common sense not based on any evidence in the record lacks substantial evidence support. *In re Zurko*, 258 F.3d 1379, 59 USPQ2d 1693 (Fed. Cir. 2001).

Even if all of the features recited in a claim are known in the prior art, it is still not proper to reject a claim on the basis of obviousness unless there is an identified valid reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. *KSR International Co. v. Teleflex Inc.*, U.S., No. 04-1350, April 30, 2007.

A determination of patentability must be based on evidence of record. *In re Lee*, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002).

It is respectfully submitted that the Action from which this appeal is taken does not meet these burdens.

The 37 CFR 1.131 Declaration

The issue of Appellants' Declaration filed September 27, 2000 is an appealable matter.

Appellants respectfully submit that the filed Declaration effectively swore back to a date prior to March 7, 1994 for at least claims 24 and 45. Thus, a date prior to March 7, 1994 is the critical date of claims 24 and 45.

The Office has provided no reasonable explanation as to why the Declaration exhibit's drawer, which includes a movable barrier for opening and closing an opening, does not constitute or include a door. McDonald refers to his drawers (10) as doors (e.g., col. 4, lines 23-26). That is, McDonald provides evidence that one skilled in the *medical art* recognizes that a drawer comprises a door.

Additionally, Appellants' possession of what is shown in the Declaration carries with it possession of variations and adaptations which would have been obvious, at the same time, to one of ordinary skill in the art. It follows that Appellants are also entitled to the date indicated in the Declaration for additional subject matter which would have been obvious to one having ordinary skill in the art (MPEP § 715.02). For example, if it was obvious to one having ordinary skill in the art to substitute a door for a drawer, then Appellants are also entitled as a result of the reduction to practice established by their Declaration, to a reduction to practice of a system which includes a door on a date prior to March 7, 1994.

As discussed in detail later, several of the rejections rely on a reference teaching a "drawer" instead of a "door". As the Office is alleging that a "drawer" includes a "door" (or does not differ therefrom), and/or that it would have been obvious to one having ordinary skill in the art to substitute a door for a drawer, then this provides further evidence that Appellants'

Declaration establishes a reduction to practice prior to March 7, 1994. Specifically, as the Declaration proves a reduction to practice of a system with a drawer, this also shows that Appellants are entitled to claim a reduction to practice of a system which included a door (as a part or as an obvious variation of the drawer) on a date prior to March 7, 1994. The Office can't have it (the use of "door") both ways. Either on one hand a "door" differs from and is not obvious in view of a "drawer" (in which case the rejections are invalid), or on the other hand Appellants are entitled to claim a reduction to practice for a system which included a door on a date prior to March 7, 1994.

Appellants respectfully submit that the Office's repeated assertions in presenting rejections that a "drawer" corresponds to a "door" establishes that Appellants have proven by the Office's admissions that a "door" is included as part of a "drawer", and that a reduction to practice of at least claims 24 and 45 prior to March 7, 1994 has been proven.

The Action's (at page 2) indicated reason ("signed only by inventor R. Michael McGrady") for refusing to accept the Declaration is not a legally valid reason. A declaration is permitted to be signed by less than all of the inventors. For example, a "declaration by less than all named inventors of an application is accepted where it is shown that less than all named inventors of an application invented the subject matter of the claim or claims under rejection" (MPEP § 715.04(B)), and "where all of the named inventors of a pending application are not inventors of every claim of the application, any affidavit under CFR 1.131 could be signed by only the inventor(s) of the subject matter of the rejected claims" (MPEP § 715.04).

The Remand (on page 5) stated that "A cursory review of the declaration, however, shows that it is not accompanied by (1) any evidence *documenting* the asserted activities *leading to* the

alleged reduction to practice (see 4b) or (2) a satisfactory explanation for the absence of such evidence". As best understood, the Remand alleges that Appellants have not established *diligence* from conception to (actual or constructive) reduction to practice. Appellants respectfully submit that 37 CFR 1.131 does not always require that diligence be shown. The Declaration shows evidence of *actual reduction to practice* of the invention prior to March 7, 1994. Because of this showing of actual reduction to practice, diligence is not an issue. Note MPEP § 715.07 (III) for discussion of the three ways in which Appellants can show prior invention. Appellants have met this MPEP section's discussed way (A), which does *not* require a showing of diligence.

Lavigne, Colson '450, and Pearson do not constitute prior art

The Parent Applications

The present application is a continuation-in-part (CIP) of application 08/927,593 filed September 11, 1997. Application 08/927,593 is a CIP of application 08/361,783 (now Patent 5,790,409) filed December 16, 1994. In addition, numerous elements of pending claims are disclosed in earlier applications from which this Application claims priority, including Application Number 08/009,055 filed January 25, 1993 (now U.S. Patent 5,404,384) and Application Number 08/186,285 filed January 25, 1994 (now U.S. Patent 5,533,079).

Claims find support in parent patent 5,790,409

Claim 45 is reproduced below to show that the recited subject matter has support in parent Patent 5,790,409 (application 08/361,783 filed December 16, 1994). Claim 24 is similar in scope to claim 45. The claim 45 is reproduced having referenced column and line locations corresponding to Patent 5,790,409 inserted therein. Of course, it should be understood that these

referenced locations are for discussion purposes only and that the claim is not limited to the embodiment presented. No unnecessary limitations are to be implied from using such references in the present claim for purposes of illustration. The present invention is not limited to the details, features and relationships shown or described in the prior Patent 5,790,409 or the pending application.

Claim 45 (reproduced)

A system for providing medical items comprising:

(Col. 3, lines 20-63) a computer (84; 86), wherein the computer is in operative connection with the data store (Col. 3, lines 22-26; Col. 10, lines 31-34), wherein the data store includes user data representative of a plurality of authorized users (Col. 3, lines 22-26; Col. 8, lines 43-58), item data representative of a plurality of medical items (Col. 3, lines 22-26; Col. 4, lines 8-12; Col. 9, lines 20-36), and location data (Col. 3, lines 22-26; Col. 9, lines 20-36) representative of storage locations in which the medical items are stored;

a user interface (Col. 3, lines 20-22; Col. 8, lines 15-17) in operative connection with the computer, wherein the interface includes at least one input device (Col. 9, lines 42-47; Col. 8, lines 15-24);

(Col. 16, lines 11-33) a housing (Col. 16, lines 17-19), wherein a storage location for at least one medical item is located in an interior area of the housing, the housing including a door (96), wherein access to the storage location is controlled by opening and closing the door (Col. 16, lines 19-23);

a lock (Col. 16, lines 19-23) in operative connection with the housing, wherein the lock is in operative connection with the computer (Col. 16, lines 53-57, 24-33), and wherein the lock is operative responsive to at least one signal from the computer to change the lock from a locked to an unlocked condition (Col. 16, lines 53-57), wherein in the locked condition the door is prevented from being opened and in the unlocked condition the door is enabled to be opened;

wherein responsive to a user inputting through the at least one input device identification data (Col. 8, lines 28-42) corresponding to data for an authorized user stored in the data store (Col. 8, lines 28-42), the computer enables the user to input item indicia corresponding to a medical item through the at least one input device (Col. 17, lines 1-12, 49-54; Col. 8, lines 9-17; Col. 16, lines 46-57), and wherein the computer is operative responsive to input of the item indicia to output the at least one signal changing the lock to the unlocked condition (Col. 16, lines 26-30, 54-57; Col. 17, lines 9-13).

If the Board should agree with the Office's position that a "drawer" (as in Appellants' reduction to practice) is the same as a "door", then (as shown above) each recited feature in at

least pending claim 45 (and claim 24) has basis in Patent 5,790,409 (filed December 16, 1994), from which the present application claims priority. As a result, at least claims 24 and 45 are entitled to a critical date prior to March 7, 1994. Thus, Appellants respectfully submit that Lavigne, Colson '450, and Pearson do not constitute prior art against at least claims 24 and 45, *especially under 35 U.S.C. § 102(b)*.

Lavigne Does Not Constitute Prior Art

Lavigne's effective filing date (March 2, 1995) is later than both the filing date (December 16, 1994) of parent patent 5,790,409 and the critical date prior to March 7, 1994. Thus, Lavigne cannot constitute prior art against at least claims 24 and 45.

Colson '450 Does Not Constitute Prior Art

Colson '450 has an effective filing date of August 2, 1994, which is later than Appellants' critical date (prior to March 7, 1994). Thus, Colson '450 cannot constitute prior art against at least claims 24 and 45.

Colson '450 was granted on a CIP application of Colson '297. Colson '297 does not include Appellants' recited claim features for which Colson '450 was applied in the Action. Specifically and by way of example and without limitation, Colson '297 (explained in more detail hereinafter with regard to the 35 U.S.C. § 102(b) rejection of claim 45) does not disclose or suggest a data store including “data representative of a plurality of authorized users”, or “data representative of a plurality of medical items”, or “data representative of storage locations in which the medical items are stored”, or the input of “identification data corresponding to data for an authorized user stored in the data store”, or enabling a “user to input item indicia” in response thereto (e.g., claim 45). Colson '297 does not include the features for which the newer Colson

'450 is being relied upon. Even if it were somehow possible for Colson '450 to have included the recited features, Colson '450 is not entitled to the earlier filing date of Colson '297 for the recited features.

Furthermore, because Colson '297 does not disclose or suggest the recited features, Appellants do not need to swear behind the Colson '297 reference in order to establish patentability of the present invention.

Pearson Does Not Constitute Prior Art

For purposes of this appeal, Pearson at best has an effective filing date of March 7, 1994, which is later than the date to which Appellants are entitled (prior to March 7, 1994). Thus, Pearson cannot constitute prior art against at least claims 24 and 45.

The actual filing date of the Pearson reference is February 12, 1996. Pearson claims priority to several earlier applications. Pearson is a continuation of Pearson 5,490,610 (filed April 13, 1995), which is a continuation of abandoned Application Serial Number 206,877 (filed March 7, 1994), which is a CIP of Pearson (US 5,292,029) ("Pearson '029).

However, it is respectfully submitted that Pearson can claim a priority date no earlier than March 7, 1994, which is the filing date of Pearson's Application Serial Number 206,877. This is because Application 206,877 is a CIP of Pearson '029. Thus, March 7, 1994 is the date in which Application 206,877 (and Pearson) relied on new subject matter (not found in Pearson '029) to support the invention therein. This new matter was critical to the issued Pearson. Thus, at best, March 7, 1994 is the critical reference date of Pearson.

As evidenced by the lack of a Pearson '029 rejection in the Action, by inference the Office admits that Pearson '029 does not disclose the features that were considered pertinent to

the pending claims. Specifically and by way of example and without limitation, Pearson '029 does not disclose or suggest a "data store" including "data representative of a plurality of authorized users", or the input of "identification data corresponding to data for an authorized user stored in the data store", or enabling a "user to input item indicia" in response thereto (e.g., claim 45). There is no indication that Pearson '029 includes a "data store" in the manner recited. Nor does Pearson '029 disclose determining that the user is an authorized user. There is no indication that Pearson '029 is concerned with input of identification data corresponding to data for an authorized user stored in the data store. In Pearson '029 the nurse (user) merely inputs the patient's ID into the keyboard (Col. 5, lines 16-17) during operation to obtain the medication. It is respectfully submitted that Pearson '029 does not disclose the recited features. Pearson '029 does not include the features for which the newer Pearson is being relied upon. Even if it were somehow possible for Pearson to have included the recited features, Pearson is not entitled to the earlier filing date of Pearson '029 for these recited features.

In conclusion, the claim 24 and/or claim 45 rejections are obviated in the following issues:

Issue #2 based on Lavigne.

Issue #3 based on Colson '450.

Issue #4 based on Pearson.

Issues #9 and #10 based on Lavigne.

Issue #10 based on Colson '450.

The 35 U.S.C. § 112, Second Paragraph, Rejections

(Issue #1)

Claims 27-43 were rejected under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which Appellants regard as the invention. The Appellants respectfully traverse the rejections. The rejections are specifically directed to claims 27, 31, and 36.

Claim 27

The Action alleges insufficient basis for "the determination that the medical item is stored in the interior area". Appellants respectfully disagree. In reviewing a claim for compliance with 35 U.S.C. § 112, second paragraph, the Office must consider the claim as a whole. Appellants respectfully submit that the Office has not considered the claim as a whole.

Antecedent basis support for the language "the determination that the medical item is stored in the interior area" recited in the "generating" step can be found in the "determining" step. The "determining" step recites "determining with a computer in operative connection with the data store, the lock module and the input device, that the type of medical item corresponding to the input is stored in the interior area". That is, the "determining" step is directed to determining . . . that the . . . medical item . . . is stored in the interior area. The "generating" step recites "generating a signal with the computer responsive to the determination that the medical item is stored in the interior area". One skilled in the art of patent law would understand that "the determination" refers to the "determining". Claim 27 is not indefinite, but rather fully meets the requirements of 35 U.S.C. § 112, second paragraph.

Claim 31

The Action alleges that there are a plurality of "other locations" with no way of distinguishing which one is the other. Appellants respectfully disagree. Appellants respectfully decline to limit the claim to a single "other location".

Claim 31 depends from claim 27. Claim 27 recites a "placing" step including "placing a medical item in the interior area of the refrigerator". Claim 27 further recites a "storing" step including "storing in a data store data representative of a type associated with the medical item placed in the interior area". Claim 31 recites that the placing step further includes placing medical items in a plurality of storage locations, at least one of the locations being in the interior area and at least one other location being outside the interior area. Claim 31 further recites that the storing step includes storing data representative of the types of medical items stored respectively in the location in the interior area and in the other location. Clearly, the "other location" is outside the interior area. Thus, the allegation of indefiniteness is unfounded. Claim 31 complies with the requirements of 35 U.S.C. § 112, second paragraph.

Claim 36

The Action alleges that it is not apparent how the door controls the access. Apparently the Examiner does not understand how a refrigerator door controls access to the interior area of a refrigerator.

Claim 36 depends from claim 27. Claim 36 recites that "access to the interior area is controlled by a refrigerator door". That is, access to the interior area of the refrigerator (claim 27) is controlled by the refrigerator door. Claim 36 further recites "opening the refrigerator door, whereby the interior area is accessible". That is, when the door is open, then the interior area of the refrigerator is accessible. In other words, entry to the interior of the refrigerator is controlled

by the position of the refrigerator door. Even infants skilled with the knowledge of how to open a refrigerator door gain understanding that it is the door which controls access to the interior of the refrigerator. Similarly, leaving one's house door open can provide access for even a skunk. Claim 36 meets the requirements of 35 U.S.C. § 112, second paragraph.

In conclusion, the claims 27-43 meet the requirements of 35 U.S.C. § 112, second paragraph. Thus, it is respectfully submitted that the 35 U.S.C. § 112, second paragraph, rejections are improper and should be withdrawn.

The 35 U.S.C. § 102 Rejections

The Office has admitted that a drawer (as was used in Appellants' prior reduction to practice) includes a door as recited in the pending claims, by basing anticipation rejections for the claims which recite a door on references which disclose a drawer. However, Appellants would like to point out that if the BPAI determines that a drawer does not include a door, then each rejection that relies on a reference's "drawer" for the recited "door" is not a legally valid rejection.

The Claims Are Not Anticipated By Lavigne

(Issue #2)

Claims 1, 3, 9, 24-25, 27, 31-33, 36-38, 42-44, and 48-50 were rejected pursuant to 35 U.S.C. § 102(b) as being anticipated by Lavigne. These rejections are respectfully traversed.

The Appellants would like to point out that the Office's need to additionally rely on Aten in the (Issue #9) 35 U.S.C. § 103(a) rejection of claims 1, 3, and 24-25 based on Lavigne in view of Aten constitutes an admission by the Office that Lavigne alone does not anticipate claims 1, 3, and 24-25.

Claim 1

Claim 1 is an independent claim which is specifically directed to a "system for providing medical items". The claim specifically recites that "the lock module is operative responsive to a signal from the computer to change the lock module from a locked to an unlocked condition" and "the computer is operative responsive to input of the item indicia to output the signal changing the lock module to the unlocked condition".

The Action alleges that Lavigne discloses a "lock responsive to the computer (col. 11 L 39-43)"; "the computer operative to output a signal which changes the lock (col. 11, L 39-43; col. 8, L 59-62)"; and that the "computer is operative responsive to input of the item indicia to unlock

the module (col. 8, L 24-30; col. 8 L 58-59)". The Appellants respectfully disagree. The relied upon section read:

"A patient identification number, obtained from the operator's keypad entry. The identification of the supervisor, the pharmacist or the operator in physical control of the carrier, through their respective data keys and obtained from the data key reader 73 (FIG. 3)" (col. 8, lines 24-30).

"Recording (for a print out of a patient record) running" (col. 8 lines 58-59).

"The door locking mechanism 139 is engaged, as determined by the microcontroller 83 which provides the lock command over lines 145" (col. 8, lines 59-62).

"If the temperature violation has occurred in the drawers 37, then the door 21 will lock, because the microcontroller 83 causes the locking solenoid 139 to lock. If a temperature violation occurs in the refrigerated drug drawer 47, then the door 21 can still be opened" (col. 11, lines 39-43).

In Lavigne, when the person (e.g., an emergency medical technician) in control of the carrier wishes to administer a drug, they can freely open the door (21), open a drawer (37, 41, 43), remove the desired drug from the carrier, and then administer the drug to the patient (col. 14, lines 34-45). The operator can later record the administration of a drug by entering a code into memory. As Lavigne makes amply clear, the door (21) of his medication carrier is always unlocked (especially for the desired emergency use) except in circumstances when an out of range temperature condition has been sensed, in which case the door will lock because a temperature violation could have damaged the medications (see col. 11, lines 37-43).

The controller in the Lavigne carrier monitors the temperature of the temperature sensitive medications held therein. If the temperature goes out of range, the controller in Lavigne operates a locking solenoid (139) which operates to *lock* the door (21) and hold it in a closed position (col. 11, lines 37-43; col. 7, lines 24-26). This alerts the user to the fact that the drugs in the carrier may have been subject to spoilage due to an out of temperature condition. This

lockdown prevents the emergency medical technician from administering a bad drug. An out of temperature condition (e.g., locked door 21) typically can only be cleared by a pharmacist using a pharmacist key (col. 12, lines 60-63) to resets the controls (col. 11, lines 3-12). However, a user is able to open the door (21) through a mechanical override if the user needs to obtain access to the medications even when there has been an out of temperature condition (col. 12, line 64 to col. 13, line 2). Lavigne's use of a "key" is to provide for accountability of the drugs inside the carrier by identify those persons (by their ID key) who had possession of or access to those drugs. That is, the drugs are easily accessible to the emergency medical technician because the unlocked door can be freely opened.

Lavigne does not disclose using a computer to change a lock module from a locked to an unlocked condition. Claim 1 recites that "the lock module is operative responsive to a signal from the computer to change the lock module from a locked to an *unlocked* condition". Lavigne, at best, is only capable of *locking* the door (21). Lavigne does not disclose using a computer to unlock a lock module, especially in the manner recited.

Lavigne also does not disclose that a "computer is operative responsive to input of the item indicia to output the signal changing the lock module to the unlocked condition". Lavigne does not disclose using a computer, which responds to inputted item indicia data, to output a signal to change a lock module from a locked condition to an unlocked condition. It follows that Lavigne's door (21) is not unlocked by a computer in response to inputted item indicia data.

Furthermore, nothing in Lavigne corresponds "identification data" input by a user to data stored in a data store. The memory on the Lavigne carrier holds information of the person having possession of the carrier at any given time. However, there is no teaching in Lavigne that the

information input concerning the person having custody of the carrier is corresponded to a listing of "authorized users".

Claim 1 further specifically recites that responsive to the input of identification data corresponding to an authorized user, a user is enabled to input data corresponding to a medical item. Again, nothing in Lavigne teaches that a user is enabled to input indicia corresponding to a medical item responsive to the input of identification information corresponding to an authorized user in a database.

Additionally, claim 1 recites that responsive to the input of the medical item indicia (which input activity is permitted when the identification data input corresponds to an authorized user), the computer is caused to output a signal that changes the lock module controlling the door of the refrigerator to an unlocked condition. Nothing in Lavigne teaches controlling a lock to unlock the door (21) in response to medical item indicia. Again, the door (21) of the medication carrier is always unlocked except in extreme circumstances when an out of range temperature condition has been sensed, in which case the door will lock (not unlock) because a temperature violation could have damaged the medications (see col. 11, lines 37-43).

It is respectfully submitted that claim 1 recites numerous features and relationships which are absent in Lavigne. Thus, Lavigne does not anticipate claim 1.

Claim 3

Claim 3 depends from claim 1 and further recites that "the lock module further comprises a door sensor, wherein the door sensor is operative to generate an open signal responsive to opening the door, and wherein the computer is operative responsive to the open signal to change the lock module to the locked condition, wherein when the door is next returned to a closed condition the door is held therein".

Appellants respectfully submit that Lavigne does not disclose a computer operative responsive to an open door signal to change a lock module to a locked condition. In Lavigne, if the temperature goes out of range, the controller of Lavigne operates a locking solenoid (139) which operates to lock the door (21) in a closed position (col. 11, lines 37-43; col. 7, lines 24-26). That is, the controller of Lavigne operates the locking solenoid (139) based on sensing temperature conditions, not on sensing whether the door was opened. In Lavigne the door (21) may be opened many times without initiating the locking solenoid (139) (col. 9, lines 7-10; col. 14, lines 34-37; col. 12, lines 15-18).

The Lavigne system senses the opening of a door to record an event in memory. However, this sensing of the door opening in no way causes a lock to change its condition so that when the door of the Lavigne carrier is thereafter closed, it is held closed and locked. The portion of the Lavigne reference cited against claim 3 in the Action (col. 6, lines 47-56) only indicates that sensors are included for sensing when drawers of the Lavigne carrier have been opened. Nothing in Lavigne discloses that in response to sensing the opening of a drawer, a lock condition is changed so that the door will be locked the next time it is closed, as is specifically recited in claim 3. Lavigne does not anticipate claim 3.

Claim 9

Claim 9 depends from claim 1. Lavigne further does not teach the recited sensor nor the refrigerator/sensor/computer relationship. Where does Lavigne teach a computer that, in response to a refrigerator door open signal generated from a sensor, stores data representative of the refrigerator door opening in the data store? Lavigne does not anticipate the claim. Even the Office admits (at Action page 17) that Lavigne does not anticipate claim 9.

Claim 24

Note Appellants' remarks in support of the patentability of claim 1. Claim 24 is an independent claim which is specifically directed to a "system for providing medical items". The claim specifically recites that "the lock module is operative responsive to a signal from the computer to change the lock module from a locked to an unlocked condition". The claim further recites that "the computer is operative responsive to input of the item indicia to output the signal changing the lock module to the unlocked condition".

Lavigne does not disclose the recited features and relationships. The Action alleges that Lavigne discloses a "lock responsive to the computer (col. 11 L 39-43)"; "the computer operative to output a signal which changes the lock (col. 11, L 39-43; col. 8, L 59-62)"; and that the "computer is operative responsive to input of the item indicia to unlock the module (col. 8, L 24-30; col. 8 L 58-59)". The Appellants disagree.

As previously discussed (e.g., see the claim 1 remarks), in Lavigne when the person in control of the carrier wishes to administer a drug, they can freely open the door (21) or open a drawer (37, 41, 43), remove the desired drug from the carrier, and then administer the drug to the patient (col. 14, lines 34-45). As Lavigne makes amply clear, the door (21) of his medication carrier is always unlocked except in circumstances when an out of range temperature condition has been sensed, in which case the door will lock (not unlock) because a temperature violation could have damaged the medications (see col. 11, lines 37-43).

Appellants respectfully submit that Lavigne does not disclose a computer operative responsive to an input of item indicia to output a signal changing the lock module to the unlocked condition. Lavigne does not disclose using a computer, which responds to inputted

item indicia data, to output a signal to change a lock module from a locked condition to an unlocked condition. Lavigne's door (21) is not unlocked by a computer in response to inputted item indicia data.

Furthermore, as previously discussed, nothing in Lavigne compares identification information input by a user to data stored in a data store. The memory on the Lavigne carrier holds information corresponding to the person having possession of the carrier at any given time. However there is no disclosure in Lavigne that the information input concerning the person having custody of the carrier corresponds to a listing of "authorized users".

Claim 24 further specifically recites that responsive to the input of identification data corresponding to an authorized user, a user is enabled to input data corresponding to a medical item. Again, nothing in Lavigne discloses that a user, responsive to authorized user input, is permitted to input indicia corresponding to a medical item.

Additionally, claim 24 specifically recites that responsive to the input of the medical item indicia (which activity is enabled when the identification data input corresponds to an authorized user), the computer is caused to output a signal, which signal changes the lock module controlling the door of the housing structure to an unlocked condition. Nothing in Lavigne discloses controlling a lock to open the door (21) in response to input of medical item indicia. Again, Lavigne's door (21) is always unlocked except in circumstances when an out of range temperature condition has been sensed, in which case the door will lock (not unlock) because a temperature violation (see col. 11, lines 37-43).

Claim 24 further specifically recites that the lock module for the door is "mounted on" an *exterior* surface of the housing structure. Lavigne also does not teach this recited feature. At

best, Lavigne has a locking solenoid (139) that can fire to lock a door (21), but the locking solenoid (139) is located *inside* an exterior case (19).

It is respectfully submitted that claim 24 recites numerous features and relationships which are not disclosed in Lavigne. Lavigne does not anticipate claim 24.

Claim 25

Claim 25 depends from claim 24 and recites that "the lock module further includes a door sensor in operative connection with the door and the computer". Claim 25 further recites that a "latching device is operative to hold the lock module in the unlocked position responsive to the signal". Claim 25 further recites that "the computer is operative to cause the output of a further signal, wherein the further signal changes the lock module to a locked condition and thereafter the latching device holds the lock module in the locked condition". Claim 25 further recites that "the computer is operative to cause the further signal to be output responsive to the earlier of at least one of the door sensor sensing opening of the door and the passage of a time delay period after output of the signal without the door sensor sensing opening of the door".

Appellants respectfully submit that Lavigne does not disclose a computer operative responsive to a sensor sensing opening of a door to change a lock module to a locked condition. Nor does Lavigne disclose a computer operative responsive to a time delay period to change a lock module to a locked condition. In Lavigne, if the temperature goes out of range, the locking solenoid (139) is operated to lock the door (21) in a closed position (col. 11, lines 37-43; col. 7, lines 24-26). That is, the locking solenoid (139) operation is based on sensing temperature conditions, not on sensing whether the door was opened or the passage of a time delay period. In

Lavigne the door (21) may be opened many times without initiating the locking solenoid (139) (col. 9, lines 7-10; col. 14, lines 34-37; col. 12, lines 15-18).

The Lavigne system senses the opening of a door to record an event in memory. However, Lavigne does not disclose or suggest that the sensing of a door opening or the passage of a time delay period causes a lock to be held in a locked condition. Lavigne's operation based on temperature is different from an operation based on door position or a time period.

The portion of the Lavigne reference cited against claim 25 in the Action (col. 6, lines 47-56; col. 7, lines 10-35) only indicates that sensors are included for sensing when *drawers* of the Lavigne carrier have been opened (col. 6, lines 47-56) and locking solenoid (139) operation (col. 7, lines 10-35). Nothing in Lavigne discloses that in response to sensing the opening of a drawer or the passage of a time delay period, a lock module is changed to a locked condition and held in the locked condition, as is specifically recited in claim 25.

Furthermore, if a "drawer" differs from a "door", then even if it were somehow possible (which it isn't) for Lavigne's "drawer" to teach the recited features, the claim is directed to a "door".

Furthermore, claim 25 recites that "the computer is operative to cause the further signal to be output responsive to the earlier of at least one of the door sensor sensing opening of the door and the passage of a time delay period after output of the signal without the door sensor sensing opening of the door". Lavigne does not disclose passage of a period of time measured after the output of the signal. Nor does Lavigne determine the earlier of either sensing the opening of the door or the passage of the time delay period. Lavigne does not anticipate claim 25.

Claim 27

Note Appellants' remarks in support of the patentability of claims 1 and 24. Lavigne does not teach enabling access to the interior area of a refrigerator via an input corresponding to the type of medical item stored in the interior area. Where does Lavigne teach that responsive to the input of a medical item type, a computer can determine that the inputted type of medical item is stored in the interior area of a refrigerator, and the computer can generate a signal responsive to the determination to enable access to that interior area of a refrigerator? Nothing in Lavigne teaches controlling a refrigerator lock to selectively open in response to an inputted medical item type corresponding to a medical item stored in a refrigerator. As previously discussed, Lavigne makes amply clear that the door (21) of his medication carrier is always unlocked except in circumstances when an out of range temperature condition has been sensed, in which case the door will lock because a temperature violation (which could have damaged the medications) has occurred (see col. 11, lines 37-43). Lavigne does not anticipate claim 27.

Claim 31

Claim 31 depends from claim 27. Lavigne further does not teach storing in a data store data representative of types of medical items stored respectively in the interior area location and in an other location, especially at the relied upon col. 9, lines 17-34. Lavigne does not anticipate claim 31.

Claim 32

Claim 32 depends from claim 31/27. Lavigne further does not teach placing a first type of medical item in the storage location in the interior area and a second type of medical item in the other storage location, especially at the relied upon col. 7, lines 36-52.

The Action is silent as to where Lavigne teaches displaying on a display device, indicia representative of both the first type of medical item and the second type of medical item. Nor can it. Lavigne does not anticipate claim 32.

Claim 33

Claim 33 depends from claim 31/27. Lavigne further does not teach a refrigerator and a dispenser in the manner recited. Lavigne does not teach determining with a computer that an inputted second type of medical item is stored in a dispenser, and dispensing the second type of medical item from the dispenser responsive to a second computer signal, especially at the relied upon col. 6, lines 20-59. Where does Lavigne generate first and second signals with a computer in regard to first and second types of medical items? Where does Lavigne teach the recited dispensing? Lavigne does not anticipate claim 33.

Claim 36

Claim 36 depends from claim 27. Lavigne further does not teach the recited refrigerator/sensor/computer relationship nor the sensing and storing. Where does Lavigne teach sensing that a refrigerator door has been opened, and storing data representative of the door opening? Lavigne does not anticipate the claim.

Claim 37

Claim 37 depends from claim 36/27. Lavigne further does not teach storing data representative of a plurality of users authorized to access medical items in the interior area of a refrigerator, and comparing whether inputted data corresponds to an authorized user, especially at the relied upon col. 10, lines 27-39. As previously discussed, Lavigne does not teach comparing

(with a computer) data input through an input device to authorized user data stored in a data store. Lavigne does not anticipate claim 37.

Claim 38

Claim 38 depends from claim 37/36/27. Lavigne further does not teach that when a user is authorized and the refrigerator door opening is performed, then data representative of the authorized user is stored in correlated relation with data representative of opening the door, especially at the relied upon col. 10, lines 27-39. Where does Lavigne teach storing data that correlates a particular user to refrigerator interior access? Lavigne does not anticipate claim 38.

Claim 42

Claim 42 depends from claim 27. Lavigne further does not teach allowing a user to open a door to access to an interior area of a refrigerator responsive to determining that the user is an authorized user. Nor does Lavigne teach that if an openable door was not opened within a time period, then operating a computer to cause the lock module to hold the door closed. Lavigne does not teach the features, especially at relied upon col. 10, lines 27-39. Lavigne does not anticipate claim 42. Even the Office admits (at Action page 17) that Lavigne does not anticipate claim 42.

Claim 43

Claim 43 depends from claim 42/27. Lavigne further does not teach storing in a data store, data representative of a door being able to be opened by the one authorized user, but not being opened, especially at relied upon col. 10, lines 27-39. Lavigne does not anticipate claim 43. Even the Office admits (at Action page 17) that Lavigne does not anticipate claim 43.

Claim 44

For sake of brevity, note Appellants' remarks in support of the patentability of claim 27. As previously discussed, nothing in Lavigne teaches controlling a housing structure lock to selectively open in response to an inputted medical item type corresponding to a medical item placed in the housing structure. As previously discussed, Lavigne makes amply clear that the door (21) of his medication carrier is always unlocked except in circumstances when an out of range temperature condition has been sensed, in which case the door will lock (not unlock) because a temperature violation (which could have damaged the medications) has occurred (see col. 11, lines 37-43). For the many reasons already discussed, it follows that Lavigne does not anticipate claim 44. Additionally, even the Office admits (at Action page 17) that Lavigne does not anticipate claim 44.

Claim 48

Note Appellants' remarks in support of the patentability of claims 1, 24, 27, and 44. Lavigne does not teach that responsive to received input corresponding to an authorized user, a computer allows input to be received that corresponds to a particular medical item represented in a data store, and wherein responsive to received input corresponding to the particular medical item, the computer causes a lock (that controls access to a medical item storage location where the particular medical item is located) to be changed from a locked condition to an unlocked condition to permit access to the storage location. Lavigne does not teach that a computer allows a user to provide input corresponding to a particular medical item, after identifying the user as an authorized user. Nor does Lavigne teach that the computer, responsive to receiving allowed input (input allowed by the authorized user) that corresponds to the particular medical item,

unlocks a lock to permit access to a storage location where the particular medical item is located. Lavigne teaches neither the recited features nor the recited relationships.

Again as Lavigne makes amply clear, the door (21) of his medication carrier is always unlocked except in circumstances when an out of range temperature condition has been sensed, in which case the door will lock (not unlock) because a temperature violation could have damaged the medications (see col. 11, lines 37-43). Nowhere does Lavigne teach that the door (21) becomes unlocked in response to receiving input to a particular medical item. Lavigne does not anticipate claim 48.

Claim 49

Claim 49 depends from claim 48. For reasons already discussed, Lavigne's door (21) cannot constitute the recited door. Lavigne's door (21) is not unlocked by a computer in response to input corresponding to a particular medical item. Nor can Lavigne anticipate claim 49.

Claim 50

Claim 50 depends from claim 48. This is a situation where the Office admits that a drawer corresponds to a door. This provides the effective reduction to practice established by Appellants' Declaration for at least claims 24 and 25. However, if the Board should decide a "drawer" differs from a "door", then Lavigne further does not teach the recited drawer. At best, Lavigne has a drawer (41) used to contain controlled substances. This drawer (41) has a mechanical key lock (42) thereon (Figure 1). In order to open the drawer, an operator must manually insert a key into the key lock (42) and turn the key to unlock the drawer (41). Lavigne does not teach that a computer, responsive to receiving input that corresponds to a particular medical item, unlocks the lock (42) to permit access to a storage location where the particular

medical item is located. Lavigne's lock (42) is controlled manually, not by a computer in response to input corresponding to a particular medical item. Lavigne does not anticipate claim

50.

The Claims Are Not Anticipated By Colson '450

(Issue #3)

Claims 1, 4, 12-15, 21, 24, 27-29, 31-33, 39, 41, 44, 48, and 50 were rejected pursuant to 35 U.S.C. § 102(b) as being anticipated by Colson '450. These rejections are respectfully traversed.

The Appellants would like to point out that the Office's need to additionally rely on Lavigne in the (Issue #10) 35 U.S.C. § 103(a) rejection of claims 1 and 24 based on Colson '450 in view of Lavigne constitutes an admission by the Office that Colson '450 alone does not anticipate claims 1 and 24.

Likewise, the Action's need to additionally rely on Iwamoto in the (Issue #13) 35 U.S.C. § 103(a) rejection of claim 4 based on Colson '450 in view of Iwamoto constitutes an admission by the Office that Colson '450 alone does not anticipate claim 4.

Claim 1

The Action alleges that Colson '450 discloses that a "data store includes user data representative of a plurality of authorized users (col. 5, L 17-29; Fig. 1. #21)". However, the relied upon section of Colson '450 is not pertinent to a data store having user data representative of a plurality of authorized users. In the relied upon section the user inputs "information concerning the particular patient and information as to the person entering the data" (col. 5, lines 17-19). The patient's record (reflecting the inputted patient information and the user, e.g., the particular nurse) may be simultaneously and automatically updated (col. 5, lines 20-29). Information may even be processed in real-time (col. 3, lines 45-57). However, there is no indication that Colson '450 is concerned with the user being an "authorized user".

Colson '450 does not teach that any comparison is made of the information that is input as to the person entering the data, to any data concerning authorized users, or to any data stored in a data store. The operation of Colson '450 merely specifies that information is input, the door is unlocked, and records are updated. There is no requirement to match identification data.

Appellants respectfully submit that Colson '450 does not disclose the capability of inputting identification data through an input device corresponding to the data representative of an authorized user stored in a data store. Colson '450 does not use data representative of an authorized user. Nor does Colson '450 use data representative of an authorized user stored in a data store.

Furthermore, Colson '450 does not disclose that in response to a user inputting identification data corresponding to an authorized user, a computer enables the user to input data corresponding to a medical item through the input device. Not only does Colson '450 not teach the capability of checking whether a user is an authorized user, but Colson '450 further does not teach enabling the input of data corresponding to a medical item in response to the user inputted identification data corresponding to authorized user data.

Additionally, as previously discussed, the user in Colson '450 inputs "information concerning the particular patient and information as to the person entering the data" (col. 5, lines 17-19). Hence, it appears that the user in Colson '450 actually inputs the "information concerning the particular patient" prior to inputting the "information as to the person entering the data". This is further evidence that Colson '450 is not concerned with the user being an "authorized user". Additionally, the use of the inputted user information appears to be only for the patient's record, e.g., the nurse that supplied the medication.

Again, there is no teaching whatsoever in Colson '450 of a computer in connection with a data store having authorized user data, data representative of medical items, and data corresponding to storage locations where medical items are stored. Further, nothing in Colson '450 discloses that a user inputs identification data to an input device, and that the input data is compared to data representative of authorized users. As Colson '450 expressly indicates (col. 5, lines 17-29), a user of the Colson '450 device inputs information concerning a patient and information on the person entering the data, and the door opens. There is no teaching in Colson '450 that a comparison is made of inputted user identification data to data concerning a plurality of authorized users.

Claim 1 also specifically recites that the computer enables a user to input indicia corresponding to a medical item through an input device. As Colson '450 expressly indicates (col. 5, lines 17-29), no item indicia corresponding to a medical item is input into the Colson '450 computer. Colson '450 only inputs information concerning a patient and the person entering the data, which then causes a door to open. Nothing in Colson '450 discloses the feature of a computer enabling a user to input indicia "corresponding to a medical item" through an input device, which is specifically recited in claim 1.

Claim 1 further recites that the computer is operative responsive to input of the item indicia corresponding to a medical item, to output a signal changing a lock from a locked to an unlocked condition, enabling opening a door of the refrigerator. Again, Colson '450 does not disclose the input of indicia "corresponding to a medical item" through an input device, nor having such input data cause a computer to unlock a lock.

It is respectfully submitted that claim 1 recites numerous features and relationships which are not disclosed in Colson '450. Thus, Colson '450 does not anticipate claim 1.

Claim 4

Claim 4 depends from claim 1. Where does Colson '450 teach a lock module (which can be unlocked responsive to a computer signal) that also comprises a manual unlocking mechanism in the manner recited? Colson '450 doesn't, especially at the relied upon section (col. 4, line 65 to col. 5, line 15). Even the Office admits (at Action page 15) that Colson '450 does not teach the recited features of claim 4. Colson '450 does not anticipate claim 4.

Claim 12

Claim 12 depends from claim 1. Colson '450 further does not teach a lock module mounted in supporting connection with an external surface of a refrigerator. The latch (35) and bolt (41) in Colson '450 are internally mounted (Figures 1, 2, 4, and 5). Note, for example, Appellants' Figure 50. Colson '450 does not anticipate claim 12.

Claim 13

Claim 13 depends from claim 12/1. Nor does Colson '450 teach a bolt attached to both the front surface and side surface of a refrigerator door. As previously discussed (claim 12), the lock unit in Colson '450 is internally mounted. Colson '450 does not anticipate claim 13.

Claim 14

Claim 14 depends from claim 12/1. Nor does Colson '450 teach the recited bolt supporting bracket arrangement. Colson '450 does not anticipate claim 14.

Claim 15

Claim 15 depends from claim 14/12/1. Nor does Colson '450 teach the recited bolt supporting bracket/fasteners/cover arrangement. Colson '450 does not anticipate claim 15.

Claim 21

Claim 21 depends from claim 1. Where does Colson '450 teach the ability of the latch (35) to return to a locked condition upon closing the door in the manner recited? Colson '450 does not anticipate claim 21.

Claim 24

The Action alleges that Colson '450 discloses that a "data store includes user data representative of a plurality of authorized users (col. 5, L 17-29; Fig. 1. #21)". However, the relied upon section is not pertinent to a data store having user data representative of a plurality of authorized users. In the cited section of Colson '450, the user inputs "information concerning the particular patient and information as to the person entering the data" (col. 5, lines 17-19). The patient's record (reflecting the inputted patient information and the user, e.g., the particular nurse) may be simultaneously and automatically updated (col. 5, lines 20-29). Information may even be processed in real-time (col. 3, lines 45-57). However, there is no indication that Colson '450 is concerned with the user being an authorized user.

Appellants respectfully submit that Colson '450 does not disclose the capability of inputting identification data through an input device corresponding to data representative of an authorized user stored in a data store. Colson '450 does not use data representative of an authorized user, nor data representative of an authorized user stored in a data store.

Furthermore, Colson '450 does not disclose that in response to a user inputting identification data corresponding to an authorized user, the computer enables the user to input data corresponding to a medical item through the input device. Colson '450 does not disclose the capability of checking whether a user is an authorized user. Colson '450 does not disclose

enabling the input of data corresponding to a medical item, in response to the user inputted identification data corresponding to data for an authorized user.

Additionally, as previously discussed, the user in Colson '450 inputs "information concerning the particular patient and information as to the person entering the data" (col. 5, lines 17-19). Hence, it appears that the user in Colson '450 actually inputs the "information concerning the particular patient" prior to inputting the "information as to the person entering the data". This is further evidence that Colson '450 is not concerned with the user being an authorized user. Additionally, the use of the inputted user information appears to be only for the patient's record, e.g., the nurse that supplied the medication.

Again, there is no teaching whatsoever that Colson '450 has a computer in connection with a data store with authorized user data, data representative of medical items, and data corresponding to storage locations where medical items are stored. Further, nothing in Colson '450 discloses that a user inputs identification data to an input device, and that the input data is compared to data representative of authorized users. As Colson '450 expressly indicates (col. 5, lines 17-29), a user of the Colson '450 device inputs information concerning a patient and information on the person entering the data, and the door opens. There is no teaching in Colson '450 that a comparison is made of input user identification data to data concerning a plurality of authorized users.

Claim 24 also specifically recites that the computer enables a user to input indicia corresponding to a medical item through an input device. As Colson '450 expressly indicates (col. 5, lines 17-29), no item indicia corresponding to a medical item is input into the Colson '450 computer. Colson '450 only inputs information concerning a patient and the person entering the data, which then causes a door (25) of Colson '450 to open. Nothing in Colson '450

discloses the feature of a computer enabling a user to input indicia corresponding to a medical item through an input device, which is specifically recited in claim 24.

Claim 24 further recites that the computer is operative responsive to input of the item indicia corresponding to a medical item, to output a signal changing a lock from a locked to an unlocked condition, enabling opening a door of the housing structure. Again Colson '450 does not disclose or suggest the input of indicia corresponding to a medical item through an input device, nor having such input data cause a computer to unlock a lock.

Colson '450 also does not teach a lock module mounted on an exterior surface of a housing structure. As previously discussed, the latch (35) and bolt (41) in Colson '450 are internally mounted (Figures 1, 2, 4, and 5). Note, for example, Appellants' Figure 50.

It is respectfully submitted that claim 24 recites numerous features and relationships which are not taught by Colson '450. Colson '450 does not anticipate claim 24.

Claim 27

Note Appellants' remarks in support of the patentability of claims 1 and 24. Colson '450 does not teach enabling access to the interior area of a refrigerator via an input corresponding to the type of medical item stored in the interior area. Where does Colson '450 teach that responsive to the input of a medical item type, a computer can determine that the inputted type of medical item is stored in the interior area of a refrigerator, and the computer can generate a signal responsive to the determination to enable access to the interior area? Nothing in Colson '450 teaches controlling a refrigerator lock to selectively open in response to an inputted medical item type corresponding to a medical item stored in a refrigerator.

Colson '450 does not teach the steps of placing a medical item in the interior area of a refrigerator, and storing in a data store data representative of the type of the placed medical item.

Where does Colson '450 teach storing data that a medical item was placed in the interior area of a refrigerator? The arrangement in Colson '450 apparently relies on the visible item storage area being properly filled, not on stored data reflective of an item actually being stored. The transparent windows (29) in Colson '450 teach away from need of stored data reflective of a stored item.

Additionally, as previously discussed, in Colson '450 the user inputs "information concerning the particular patient and information as to the person entering the data" (col. 5, lines 17-19). Where does the user in Colson '450 input data corresponding to a type of medical item stored in the interior area? It follows that Colson '450 also does not determine (with a computer) that a type of medical item corresponding to the input is stored in the interior area. It further follows that Colson '450 does not generate a signal responsive to the determination, and enable access to the interior area responsive to the signal. Thus, Colson '450 does not anticipate claim 27.

Claim 28

Claim 28 depends from claim 27. As previously discussed, Colson '450 does not teach attaching a lock module to an exterior surface of a refrigerator. The latch (35) and bolt (41) in Colson '450 are internally mounted (Figures 1, 2, 4, and 5).

Claim 29

Claim 29 depends from claim 28/27. Colson '450 further does not teach attaching a bolt supporting bracket to an exterior surface of a refrigerator door with at least one fastener, and then covering the fastener by installing a cover. Where is the alleged refrigerator door exterior surface, fastener, and cover, especially at the relied upon section (col. 4, line 65 to col. 5, line 15)? Colson '450 does not anticipate claim 29.

Claim 31

Claim 31 depends from claim 27. Colson '450 further does not teach storing data that is representative of types of medical items stored respectively in an interior area location and in another location. Colson '450 does not anticipate claim 31.

Claim 32

Claim 32 depends from claim 31/27. Colson '450 further does not teach placing a first type of medical item in the storage location in the interior area and a second type of medical item in the other storage location, especially at the relied upon sections of Colson '450.

The Action is silent as to where Colson '450 teaches displaying on a display device, indicia representative of *both* the first type of medical item and the second type of medical item. Nor does Colson '450 teach the recited features and relationships, or anticipate claim 32.

Claim 33

Claim 33 depends from claim 31/27. Colson '450 further does not teach a refrigerator and a dispenser in the manner recited. Colson '450 does not teach determining with a computer that an inputted second type of medical item is stored in a dispenser, and dispensing the second type of medical item from the dispenser responsive to a second computer signal. Where does Colson '450 generate first and second signals with a computer in regard to first and second types of medical items? Colson '450 does not anticipate claim 33.

Claim 39

Claim 39 depends from claim 27. Where does Colson '450 teach manually actuating an unlocking mechanism and accessing the interior area? Colson '450 does not teach the features at relied upon col. 4, line 65 to col. 5, line 15? Colson '450 does not anticipate claim 39.

Claim 41

Claim 41 depends from claim 27. The rejection does not state where Colson '450 teaches the recited steps. Nor can it. Rather, the Examiner admits in each of Issue #22 (which relies on McDonald), Issue #23 (which relies on Weinberger), and Issue #24 (which relies on Higham) that Colson '450 alone cannot anticipate claim 41. The Appellants agree.

Claim 44

For reasons of brevity, note Appellants' remarks in support of the patentability of claim 27. As previously discussed (claim 27), Colson '450 does not teach a method involving a "refrigerator". Appellants respectfully submit that Colson '450 also does not teach the method with regard to any "housing structure". Further, where does Colson '450 compare medical item type input to data in a data store, and operating a computer to enable access to an interior area (where the medical item type is located) responsive to determining that the medical item type corresponding to the input is stored in the interior area? Colson '450 does not teach the recited method. It follows that Colson '450 does not anticipate claim 44.

Claim 48

The Action does not address where Colson '450 teaches the features of claim 48. Regardless, Colson '450 does not teach that a computer allows a user to provide input corresponding to a particular medical item, after identifying the user as an authorized user. Nor does Colson '450 teach that the computer, responsive to receiving allowed input (input allowed by the authorized user) that corresponds to the particular medical item, unlocks a lock to permit access to a storage location where the particular medical item is located. Colson '450 teaches

neither the recited features nor the recited relationships. Colson '450 does not anticipate claim 48.

Claim 50

Claim 50 depends from claim 48. The rejection relies on Colson '450 at col. 2, lines 38-55. This is a situation where the Office admits that a door is the same as a drawer. However, if the Board decides that a "drawer" differs from a "door", then Colson '450 does not teach the recited drawer. The relied upon section of Colson '450 does not mention a "drawer". Nor is the invention of Colson '450 directed to a "drawer". Colson '450 does not anticipate claim 50.

The Claims Are Not Anticipated By Pearson

(Issue #4)

Claims 45 and 48-50 were rejected under 35 U.S.C. § 102(b) as anticipated by Pearson.

Claim 45

The door feature

Pearson has a drawer (10). Pearson does not teach or even mention a "door". The assertion by the Office thus proves the validity of the reduction to practice established by Appellants' Declaration of at least claims 24 and 45 prior to March 7, 1994. However, if the Board decides that a "door" differs from a "drawer", then Pearson cannot anticipate claim 45.

The plurality of authorized users feature

In contrast to the elements recited in claim 45, the system in Pearson does not disclose a computer with a data store having stored user information corresponding to "authorized users". Further, Pearson does not have a computer that operates responsive to the input of identification data that corresponds to one of the authorized users, to enable input of indication which identifies a medical item. Pearson operates to dispense medication in the manner expressly indicated therein (e.g., col. 4, line 60 to col. 5, line 5). First a password is entered (via a keyboard; col. 3, lines 13-15) by a nurse to authorize use of the dispenser. Next the nurse enters patient identification information. Next the nurse verifies that the screen displayed by the computer corresponds to the correct patient. Then the computer unlocks each container (8) or drawer (10) holding medication that the patient is scheduled to receive at that time.

During an unscheduled request (e.g., an emergency) the dispensing of medication may also occur (col. 6, lines 6-23). However, the acting nurse has to provide their name and an

explanation for the reason of the request. The computer is able to record all pertinent information, including the medications dispensed, the amount of medication, the identity of the patient, the time dispensed, the name of the nurse, and the explanation.

Pearson does not teach a computer in operative connection with a data store, which data store includes data for a plurality of authorized users. The device of Pearson requires the user to input a password. The password appears to be a multi-user password which enables several different persons to access the dispenser (computer) using the same password. Thus, the arrangement of the dispenser (computer) of Pearson is similar to a personal computer that enables access to plural users while requiring only a single password. That is, only a single password is required to access the dispenser of Pearson. Therefore, any nurse that has been authorized to know the current password may access the medication dispenser. Pearson also teaches that the password is similar to a mechanical key (col. 4, lines 36-39).

Pearson does not teach that a computer operates in response to determining that the inputted user identification data corresponds to one of a *plurality* of different authorized users. Pearson does not teach in any manner that a plurality of different passwords are required. Nor does Pearson teach that a plurality of different passwords are required corresponding to different authorized users. Nor does Pearson teach that a plurality of different passwords are stored in a data store, where the passwords reflect data representative of a plurality of authorized users. Pearson does not teach data corresponding to a plurality of authorized users stored in a data store. Nor does Pearson teach a computer in operative connection with the data store. Nor does Pearson teach corresponding inputted identification data with that of a plurality of authorized

users' data. That is, in Pearson there is no teaching of comparing an input password to a plurality of authorized passwords in a data store.

The data store data feature

Furthermore, claim 45 specifically recites that "the computer is in operative connection with the data store, wherein the data store includes user data representative of a plurality of authorized users, item data representative of a plurality of medical items, and location data representative of storage locations in which the medical items are stored". The Action has not indicated, nor is it seen, where Pearson discloses a data store including data representative of a plurality of "authorized users", a plurality of "medical items", and "storage locations" in which the medical items are stored. Nor has the Action indicated, nor is it seen, where Pearson discloses a computer in operative connection with a data store including data representative of a plurality of authorized users, a plurality of medical items, and storage locations in which the medical items are stored.

The enablement to input medical item indicia feature

Furthermore, there is no disclosure in Pearson of the feature that a computer operates in response to determining that the inputted user data corresponds to one of a plurality of authorized users, to then enable input of indicia corresponding to a medical item. Pearson does not disclose the relationship, as specifically recited in claim 45, that the computer operates to enable the input of item indicia corresponding to a medical item responsive to receipt of identifying data corresponding to data for an authorized user among a plurality of authorized users for whom data is stored, and the computer then operating responsive to the item indicia to generate a signal changing the condition of the lock to an open condition. Additionally, as previously discussed,

Pearson fails to teach that a "data store includes user data representative of a plurality of authorized users".

The unlocking responsive to medical item input feature

Pearson also does not teach that a computer causes unlocking of a medical item housing door responsive to input of medical item indicia.

Conclusion

It is respectfully submitted that claim 45 recites numerous features and relationships which are not disclosed in Pearson. Pearson does not anticipate claim 45.

Claim 48

For reasons of brevity, note Appellants' remarks in support of the patentability of claim 45. Pearson also does not teach a computer that, responsive to receiving allowed input (input allowed by an authorized user) that corresponds to a particular medical item, causes unlocking of a lock to permit access to a storage location where the particular medical item is located. Pearson teaches neither the recited features nor the recited relationships. Pearson does not anticipate claim 48.

Claim 49

Again, Pearson does not teach or even mention a "door". Again the Office admits that a drawer (as in Appellants' reduction to practice) is the same as a door. However, if the Board decides that a "door" differs from a "drawer", then Pearson cannot anticipate claim 49.

Claim 50

Pearson does not teach that a computer, responsive to receiving input that corresponds to a particular medical item, unlocks a lock to permit access to a storage location where the

particular medical item is located. As previously discussed, Pearson operates to dispense medication in the manner expressly indicated therein (e.g., col. 4, line 60 to col. 5, line 5). First a password is entered (via a keyboard; col. 3, lines 13-15) by a nurse to authorize use of the dispenser. Next the nurse enters patient identification information. Next the nurse verifies that the screen displayed by the computer corresponds to the correct patient. Then the computer unlocks a drawer (10) holding medication that the patient is scheduled to receive at that time. Where is Pearson's drawer unlocked based on input of a particular medical item? It isn't. Pearson does not anticipate claim 50.

The Claims Are Not Anticipated By Higham

(Issue #5)

Claims 46, 48, and 50 were rejected pursuant to 35 U.S.C. § 102(e) as being anticipated by Higham. The Action's reliance on the 35 U.S.C. § 103(a) rejection of claim 46 as obvious over Higham (Issue #8) constitutes an admission by the Office that Higham alone cannot anticipate the claim.

Claim 46

Claim 46 depends on independent claim 45. Claim 45 is not rejected based on Higham. That is, independent claim 45 is deemed by the Office to be patentable over Higham.

The rejection alleges that Higham shows (with regard to claim 45) a data store having "user data representative of a plurality of authorized users (col. 13 L 30-41)". However, there is no indication that Higham's user identification information corresponds to data for an authorized user. Higham at col. 13, lines 32-33 states that "user identification information *and* patient identification information" are entered into a processor. This information is gathered for record keeping, not for authorizing usage. Why would patient identification information be needed for authorizing usage? Nor does Higham discuss or mention any need for authorization. Rather, Higham's Figure 1, with the processor (22) being located interior of the door, provides evidence that Higham does not require authorization to open the door. Higham also teaches that a prior drawback was that there was no record of who accessed the items (col. 1, lines 49-59). Access to Higham's items can now be prevented until the user and patient identification information have been recorded (e.g., col. 7, lines 33-35). This record can be used to determine which users have been accessing the receptacles (e.g., col. 6, lines 4-5).

Again, nothing in Higham compares identification information input by a user to data stored in a data store. Nor is there any disclosure or need in Higham that entered information be compared to data representative of a plurality of "authorized users".

Furthermore, nothing in Higham discloses that a user is enabled to input indicia corresponding to a medical item responsive to the input of data corresponding to an authorized user in a data store, especially to unlock a door.

Furthermore, Higham does not disclose a lock having a visual indicator (claim 46). For example, note Appellants' Figure 50 embodiment of a lock module (452) comprising a visual indicator (464). The Action alleges that Higham (at col. 11, lines 41-65) teaches a lock that comprises a visual indicator (42). This allegation is not correct.

Nor does Higham disclose that a visual indicator provides an indication responsive to a computer output signal that a "door" is enabled to be opened. In Higham, at best the visual indicators are used to indicate which "drawer" or rack has the item, and they are then used to indicate the location of the item in that particular drawer or rack (col. 7, lines 1-6). Again the Office admits that a drawer and a door are the same, validating Appellants' Declaration establishing a reduction to practice. However, if the Board decides that a "door" differs from a "drawer", then nothing in Higham discloses that a visual indicator provides an indication that a *door* is enabled to be opened. For the many noted reasons, Higham does not anticipate claim 46.

Claim 48

The Action does not address claim 48. Nevertheless, for reasons already discussed, Higham does not determine whether inputted data corresponds in a data store to an authorized user. Higham also does not teach that a computer, responsive to receiving input (from a

determined authorized user) that corresponds to a particular medical item, causes unlocking of a lock to permit access to a storage location where the particular medical item is located. Higham teaches neither the recited features nor the recited relationships. Higham does not anticipate claim 48.

Claim 50

Higham further does not teach that a computer, responsive to receiving input (from a determined authorized user) that corresponds to a particular medical item, causes unlocking of a drawer to permit access to a storage location where the particular medical item is located. Again, Higham does not teach or need to determine whether user input is that of an authorized user. Higham does not anticipate claim 50.

The Claims Are Not Anticipated By Colson '297

(Issue #6)

Claim 45 was rejected under 35 U.S.C. § 102(b) as being anticipated by Colson '297.

Claim 45

In contrast to the elements recited in claim 45, the system in Colson '297 does not teach a data store including: "user data" representative of a plurality of authorized users, "item data" representative of a plurality of medical items, and "location data" representative of storage locations in which the medical items are stored.

Colson '297 is not concerned with "authorized users". Colson '297 does not discuss or mention any need for user authorization. Furthermore, Colson '297 does not have a computer that operates responsive to the input of data that corresponds to one of the authorized users, to enable input of indica which identifies a medical item. Colson '297 operates in the manner expressly indicated therein (e.g., col. 4, lines 39-52). Inputs through a keyboard, identifying a medical item and identifying a person, cause a door to unlock. There is no teaching or need to compare input concerning the person taking the item to data store data of a plurality of authorized users. Colson '297 simply receives the data and apparently stores (records) the data for later recovery. There is no ability to compare input data to previously stored data, especially for authorizing a user.

Further there is no disclosure in Colson '297 of the feature that a computer operates in response to determining that inputted user data corresponds to one of the plurality of authorized users, to then enable input of indicia identifying a medical item. According to Colson '297, identifying information concerning a medical item can be input at any time and is apparently

input before any user information (col. 4, lines 39-52). Colson '297 further fails to disclose this feature which is expressly recited in claim 45.

Claim 45 also recites that the data store in operative connection with the computer includes location data representative of storage locations in which medical items are stored. The cited portions of Colson '297 do not disclose a data store, nor a data store including location data representative of storage locations in which particular medical items are stored. Furthermore, Colson '297 does not disclose a computer that operates to enable the input of a medical item in response to receipt of identifying data corresponding to an authorized user for whom data is stored, and the computer then operates responsive to the medical item indicia to generate a signal to change a door lock to an open condition. Colson '297 does not anticipate claim 45.

The 35 U.S.C. § 103(a) Rejections

The Appellants would like to point out that if the BPAI determines that a drawer does not include a door, then each rejection that relies on a reference's "drawer" for the recited "door" is not a legally valid rejection.

The Claims Are Not Obvious Over Lavigne

(Issue #7)

Claims 2 and 26 were rejected under 35 U.S.C. § 103(a) as obvious over Lavigne in view of Nemoto, Keskin, and Tabata.

Claim 2

Claim 2 depends from claim 1 and further recites that "the lock module further *comprises* a visual indicator, and wherein the visual indicator provides an indication responsive to the signal that the door is enabled to be opened". For example, note Appellants' Figure 50 embodiment of a lock module (452) comprising a visual indicator (464).

The rejection indicates that Lavigne only discloses "a visual indicator *proximate* the lock" at col. 11, lines 3-43. As best understood, the Action admits that Lavigne lacks a lock module that "comprises" a visual indicator.

The Action alleges that it would have been obvious to place a visual indicator on Lavigne's lock, but provides no valid reason for such modification. Rather, the provided reason actually teaches away from the recited language. The Action (on page 11) indicates that it would be better if the visual indicator were only proximate to the lock, because proximate mounting rather than precise mounting is sufficient to indicate to a user the location of the lock.

Lavigne does not disclose a lock module comprising a visual indicator. The Action has not provided any valid reason or explained why a visual indicator would be placed on a lock in

Lavigne. At best, a control module (31) in Lavigne has a visual indicator (LEDs 75) (col. 5, lines 54-57; Figure 1). Lavigne also has a locking solenoid (139) that can fire to lock a door (21), but the locking solenoid (139) is located *inside* an exterior case (19). A LED (75) located inside the exterior case (19) would not be visible and would serve no valid purpose. Thus, the LED (75) cannot constitute the recited visual indicator. The alleged modification to Lavigne is clearly an attempt at hindsight reconstruction of Appellants' claimed invention, which is legally impermissible.

Also, the Office's apparent attempt to dramatically change the structural arrangement of Lavigne would go directly against the implicit teaching of the Lavigne reference and would destroy the reference. That is, the alleged modification to Lavigne would improperly destroy the disclosed utility or operability of the Lavigne teaching. Therefore, it would not have been obvious to have provided Lavigne with a visual indicator as alleged by the Office.

Furthermore, claim 2 specifically recites that the visual indicator provides an indication that the door is enabled to be opened. In Lavigne, the indicator lights (LEDs 75) only indicate a temperature condition (col. 11, lines 25-43), not the door's opening condition. For example, if a temperature violation has occurred for the temperature sensitive items in the drawers (37), then the door (21) will lock (col. 11, lines 37-41). However, if the temperature violation has occurred in the refrigerated drawer (47) then the door (21) can still be opened (col. 11, lines 41-43). Upon an occurrence of a temperature violation one would be unable to determine from the LED whether the door (21) is enabled to be opened.

Also, placing the alleged indicator lights (LEDs 75) on a locking solenoid (139) located inside the closed exterior case (19) would not provide an indication to a user that the door (21) is

able to be opened. Rather, the door (21) would have to already be open in order to see the LED (75). Again, Lavigne's LEDs (75) cannot constitute the recited visual indicator.

Furthermore, claim 2 recites that "the visual indicator provides an indication *responsive to the signal* that the door is enabled to be opened". From claim 1, the "signal" is from a computer to change the lock module from a locked to an unlocked condition. Lavigne does not disclose or suggest that a visual indicator is responsive to a signal (from a computer) to change a lock module from a locked to an unlocked condition. Contrarily, as previously discussed, Lavigne at best only discloses changing a locking solenoid (139) from an unlocked to a locked condition. Thus, Lavigne again teaches away from the subject matter recited in claim 2. The Office has not established a *prima facie* case of obviousness.

The Office is silent as to any relevance of Nemoto, Keskin, and Tabata with regard to claim 2, especially with regard to a permanent magnet latching solenoid.

Claim 26

Claim 26 depends from claim 25/24 and further recites that "the latching device includes a permanent magnet latching solenoid". For reasons already discussed, Lavigne does not teach or suggest a lock module for a door that includes a latching device, especially where the lock module is mounted on an *exterior* surface (claim 24) of a housing structure. It follows that Lavigne cannot teach or suggest an exterior mounted latching device including a permanent magnet latching solenoid.

None of Keskin, Nemoto, and Tabata have anything to do with the relevant art of medical item dispensing systems, especially in the manner recited. The Office has not established a *prima facie* case of obviousness.

Claim 46 Is Not Obvious Over Higham

(Issue #8)

Claim 46 was rejected under 35 U.S.C. § 103(a) as obvious over Higham.

Claim 46

Claim 46 depends on independent claim 45. Claim 45 is not rejected based on Higham. That is, independent claim 45 is deemed by the Office to be patentably distinguishable over Higham.

Claim 46 recites that "the lock further comprises a visual indicator, and wherein the visual indicator provides an indication responsive to the at least one signal that the door is enabled to be opened". The Action is silent as to where Higham teaches or suggests the recited features and relationships. The Action is also silent as to why the features and relationships of claim 46 are obvious in Higham. Appellants respectfully decline to speculate. The record lacks concrete prior art evidence of record, in violation of *In re Zurko*, supra and *In re Lee*, supra. The rejections also do not identify a valid reason why one skilled in the art would have combined alleged features in the manner claimed, in violation of *KSR International Co.*, supra. Nor does the Action factually support any *prima facie* conclusion of obviousness.

Furthermore, the dependent claim 46 rejection does not address the independent claim 45 features and relationships. Appellants respectfully submit that the Examiner is also committing prejudicial error by not addressing all the recited features and relationships (including those in claim 45). This Examiner's errors deprive Appellants of their administrative due process rights (e.g., timely notice of the Examiner's position and opportunity for unhindered response thereto).

The Claims Are Not Obvious Over Lavigne In View of Aten

(Issue #9)

Claims 1, 3, 24-26, and 41 were rejected under 35 U.S.C. § 103(a) as obvious over Lavigne in view of Aten. These rejections are respectfully traversed.

Claims 1, 3, and 24-25

Appellants' remarks concerning the previously discussed anticipation rejections based on Lavigne alone (Issue #2) are herein incorporated by reference. As previously discussed, claims 1, 3, and 24-25 recite numerous features and relationships that are not found in Lavigne.

There is no evidence of record that the Examiner has properly conducted an analysis in accordance with *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). For example, where does the Action indicate the differences between the claims and Lavigne? Because the Action has not properly conducted a *Graham v. John Deere Co.* analysis, it has not met the most basic of criteria for establishing a *prima facie* case of obviousness. Since the Office has not produced a *prima facie* case of obviousness, Appellant is under no obligation to submit evidence of nonobviousness (e.g., MPEP § 2142).

The rejection is also silent as to what features in Aten are being relied upon to overcome the previously discussed deficiencies of Lavigne alone (with regard to the anticipation rejections of claims 1, 3, and 24-25). Appellants respectfully decline to speculate. Neither Lavigne nor Aten, taken alone or in combination, teach or suggest the features and relationships that are specifically recited in these claims. It is therefore respectfully submitted that the rejections should be withdrawn.

Claim 26

The only discussion in the Action concerning the combination with Aten that mentions any features recited in the rejected claims, is claim 26, which relates to the referred to "permanent magnet". Thus, as best understood, claim 26 is the only claim addressed by the Office in the stated rejection of claims 1, 3, 24-26, and 41. That is, apparently claim 26 is the only rejected claim for which the Office's rejection relies on Aten.

Claim 26 depends from claim 25/24. Claim 26 further recites that "the latching device includes a permanent magnet latching solenoid".

The Action alleges that it would have been obvious to make the dispenser of Lavigne "with a solenoid having a permanent magnet because a construction averts the need for plural windings as taught by Aten et al. (col. 9 L 1-30)". Hence, the Action admits that Lavigne lacks a latching device including a permanent magnet latching solenoid.

Appellants disagree that Aten discloses or suggest a latching device in the manner recited. Nor does Aten teach averting the need for "plural windings" as alleged in the Action. Aten teaches a notched locking wheel (86) positioned to prevent ejector pinion (34) rotation unless the wheel notch (90) is so aligned as to allow an ejector pinion pin to rotate forward. Latching mechanisms can insure that lock/unlock positions of the locking wheel are retained. One form of the latching mechanism utilizes magnets. The Action does not state in any valid manner how to combine incompatible features of Aten with Lavigne to produce the recited invention.

It is respectfully submitted that the Action fails to establish a *prima facie* case of obviousness against the claim. The modification of Lavigne with the teaching of Aten still would not have resulted in the recited invention.

Claim 41

Claim 41 depends from claim 27. By inference the Office admits that Lavigne does not teach or suggest all of the features of claim 41. The rejection is silent as to what features in Aten are being relied upon with regard to the features admitted as absent in Lavigne. Appellants respectfully decline to speculate. The Office has not established a *prima facie* case of obviousness. Nor has the Action explained how Lavigne could be modified to overcome the admission. Since the Action does not explain the rejection with reasonable specificity, it further procedurally fails to establish a *prima facie* case of obviousness. *Ex parte Blanc*, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989).

The Claims Are Not Obvious Over Colson '450 In View of Lavigne

(Issue #10)

Claims 1-3 and 24-25 were rejected under 35 U.S.C. § 103(a) as obvious over Colson '450 in view of Lavigne.

As previously discussed in the anticipation rejection based on Colson '450 (Issue #3), claims 1 and 24 recite numerous features and relationships that are not found in Colson '450. Appellants' previous remarks, concerning the rejection of claims 1 and 24 based upon the Colson '450 reference are herein incorporated by reference.

As previously discussed (Issues #2 and 7), claims 1-3 and 24-25 recite numerous features and relationships that are not also found in Lavigne. Appellants' remarks, concerning the rejections of claims 1-3 and 24-25 based upon the Lavigne reference, are also herein incorporated by reference. Neither Colson '450 nor Lavigne, taken alone or in combination, teach or suggest the recited invention.

The discussion in the rejection suggests that it is addressing only the features recited in claims 2-3 and 25-26. This is because only these claims respectively mention a "visual indicator", a "door sensor", and a "latching device". The Action is silent regarding claims 1 and 24, especially which recited features are absent in Colson '450 and the application of Lavigne.

Appellants refuse to speculate as to possible rationales for the rejections of claims 1 and 24. The Patent Office bears the burden of showing in the cited art a specific teaching or suggestion to produce the claimed combination, or a valid reason why one skilled in the art would have combined alleged features in the manner claimed. *KSR International Co.*, *supra*.

Appellants have reviewed the references cited and have determined that the cited references, taken individually or as a whole, clearly do not teach or suggest the invention recited in claims 1 and 24. Therefore, the claims would not have been obvious to one having ordinary skill in the art.

Claim 1

The Office has not established that each and every one of the features recited in the claim is known in the prior art. The rejection on the basis of Colson '450 and Lavigne does not overcome the deficiencies of the rejections already discussed, which rejections assert for example that claim 1 is anticipated by these same references (Issue #2 and Issue #3). Thus, as the Colson '450 and Lavigne references do not disclose all the elements of the claim (nor any reason, teaching or suggestion to produce the claimed combination), the rejection is further respectfully submitted to be improper on this basis.

As previously discussed, Colson '450 does not disclose the capability of inputting identification data through an input device, corresponding to the data representative of an authorized user stored in a data store. Colson '450 does not use data representative of an authorized user. Colson '450 does not use data representative of an authorized user stored in a data store. Nothing in Colson '450 discloses or suggests that a user inputs identification data to an input device, and that the input data is compared to data representative of authorized users.

As also previously discussed, nothing in Lavigne compares identification information input by a user to authorized user data stored in a data store. The memory on the Lavigne carrier only holds information corresponding to the person having possession of the carrier at any given time through their respective keys (col. 8, lines 26-29). However, as previously discussed, there

is no disclosure or suggestion in Lavigne that the information input concerning the person having custody of the carrier is compared to a listing of "authorized users". Hence, Lavigne cannot overcome the deficiencies of Colson '450 as it does not disclose or suggest the recited features which are absent in Colson '450.

Furthermore, Colson '450 does not disclose that in response to a user inputting identification data corresponding to an authorized user, a computer enables the user to input data corresponding to a medical item through the input device. Colson '450 does not disclose enabling the input of data corresponding to a medical item, in response to the user inputted identification data corresponding to data for an authorized user.

Likewise, nothing in Lavigne discloses or suggests that a user is enabled to input indicia corresponding to a medical item responsive to the input of information corresponding to an authorized user in a database. Hence, Lavigne also cannot overcome the deficiencies of Colson '450 in this matter as it also does not disclose or suggest the recited features which are absent in Colson '450.

Neither Colson '450 nor Lavigne, taken alone or in combination, disclose or suggest the features and relationships that are specifically recited in the claim. As nothing in the cited art discloses nor suggests the features and relationships that are specifically recited in the claim, and because there is no teaching, suggestion or motivation cited for combining features of the cited references so as to produce Appellants' invention, it is respectfully submitted that the claim is allowable for these reasons. Appellants also respectfully submit that dependent claims 2-3 are likewise allowable for at least the same reasons.

Claim 2

Claim 2 depends from claim 1 and further recites that "the lock module further comprises a visual indicator, and wherein the visual indicator provides an indication responsive to the signal that the door is enabled to be opened".

The rejection admits that Colson '450 alone does not disclose a visual indicator located on a lock. The Action then goes on to state (without any citation to any teaching or suggestion in the cited art) that it would be "obvious to substitute location of the visual indicator to the lock as a matter of design choice because proximate placement of a visual indicator is sufficient to indicate to the user the location of the compartment(s) and the status of the lock corresponds with the compartment access commands from the computer (col. 6, lines 47-56; col. 7, lines 10-35)". Appellants respectfully submit that this assertion is not sufficient to reject the pending claim.

The Action admits that Colson '450 does not disclose a visual indicator located on a lock. It follows that Colson '450 does not disclose a visual indicator that provides an indication responsive to a signal from a computer that can cause the lock to be changed from a locked condition to an unlocked condition.

As previously discussed (Issue #7), Lavigne also does not disclose or suggest these features. Appellants' remarks, concerning the rejection of claim 2 based on Lavigne (Issue #7), are herein incorporated by reference.

The Action alleges (in paragraph number 14) that Lavigne shows "a visual indicator proximate the lock (col. 11, L 3-43)". The Action (at said paragraph) alleges that it would have been obvious to place a visual indicator on the Lavigne's lock. Hence, the Action inherently admits that Lavigne lacks a lock module comprising a visual indicator. Appellants respectfully

submit that in Lavigne, it is the control module (31) which has a visual indicator (LEDs 75) (col. 5, lines 54-57), not a lock module. Hence, the Action itself admits that Lavigne cannot overcome the deficiencies of Colson '450 because Lavigne does not disclose or suggest the recited features which are admittedly absent in Colson '450.

Furthermore, claim 2 specifically recites that the visual indicator provides an indication that the door is enabled to be opened. In Lavigne, the indicator lights (LEDs 75) only indicate a temperature condition (col. 11, lines 25-43), not the door's locked or unlocked condition. Hence, Lavigne cannot overcome the deficiencies of Colson '450 as it does not disclose or suggest the recited features which are absent in Colson '450.

Furthermore, claim 2 recites that "the visual indicator provides an indication *responsive to the signal* that the door is enabled to be opened". From claim 1, the "signal" is from a computer to change the lock module from a locked to an unlocked condition. Lavigne does not disclose or suggest that a visual indicator is responsive to a signal (from a computer) to change a lock module from a locked to an unlocked condition. Conversely, as previously discussed, Lavigne at best only discloses changing a locking solenoid (139) from a normally unlocked condition to a locked condition. Thus, Lavigne actually teaches away from the subject matter recited in claim 2. It follows that Lavigne cannot overcome the deficiencies of Colson '450 as it does not disclose or suggest the recited features which are absent in Colson '450. The Office has not established a *prima facie* showing of obviousness.

Claim 3

Claim 3 depends from claim 1 and further recites that "the lock module further comprises a door sensor, wherein the door sensor is operative to generate an open signal responsive to

opening the door, and wherein the computer is operative responsive to the open signal to change the lock module to the locked condition, wherein when the door is next returned to a closed condition the door is held therein".

The Action admits that Colson '450 does not disclose "a door sensor; door (sensor) is operative to generate an open signal responsive to the door opening". The Action then alleges that Lavigne "discloses a door sensor with the door operative to generate an open signal responsive to the door opening". The Action further alleges that it would have been "obvious to use a sensor to detect the opening of the door as a means of saving power and recording removal of the item as taught by Colson" '450.

The Action admits that Colson '450 does not disclose a "door sensor" or that "the door sensor is operative to generate an open signal responsive to opening the door". It follows that Colson '450 lacks a lock module comprising a door sensor. It further follows that Colson '450 lacks that a "computer is operative responsive to the open signal to change the lock module to the locked condition, wherein when the door is next returned to a closed condition the door is held therein".

The Lavigne system senses the opening of a door to record an event in memory. However, the sensing of the door opening in no way causes a lock to change its condition so that when the door of the Lavigne carrier is thereafter closed, it is held closed and locked. The portion of the Lavigne reference cited against claim 3 in the Action only indicates that sensors are included for sensing when *drawers* of the Lavigne carrier have been opened. Nothing in Lavigne discloses or suggests that in response to sensing the opening of a *door* (or even a drawer), a lock condition is changed so that the door will be locked the next time it is closed.

Hence, Lavigne cannot overcome the deficiencies of Colson '450 as it does not disclose or suggest the recited features which are admittedly absent in Colson '450. The Office has not established a *prima facie* showing of obviousness.

Claim 24

Claim 24 recites numerous features and relationships that are not found in either Colson '450 or Lavigne. Lavigne cannot overcome the deficiencies of Colson '450 as it does not disclose or suggest all of the recited features and relationships which are not found in Colson '450. Neither of the references, taken alone or in combination, teach or suggest the recited features and relationships. Appellants' remarks, concerning the rejection of claim 24 by the Colson '450 reference alone (Issue #3) and by the Lavigne reference alone (Issue #2), are herein incorporated by reference.

The Action does not address claim 24, nor the relied upon features in Lavigne that are necessary to overcome the inferred deficiencies of the Colson '450 reference. Nor has any teaching or suggestion been cited to produce the claimed features and relationships. Appellants refuse to speculate concerning the unstated reasoning for the rejection of claim 24. Since the rejection also does not identify a valid reason why one skilled in the art would have combined alleged features in the manner claimed, it is also in violation of *KSR International Co.*, *supra*. The Action does not factually support any *prima facie* conclusion of obviousness.

Claim 25

Claim 25 depends from claim 24 and further recites that "the lock module further includes a door sensor in operative connection with the door and the computer". Claim 25 also recites that a "latching device is operative to hold the lock module in the unlocked position

responsive to the signal". Claim 25 further recites that "the computer is operative to cause the output of a further signal, wherein the further signal changes the lock module to a locked condition and thereafter the latching device holds the lock module in the locked condition". Claim 25 further recites that "the computer is operative to cause the further signal to be output responsive to the earlier of at least one of the door sensor sensing opening of the door and the passage of a time delay period after output of the signal without the door sensor sensing opening of the door".

The Action admits that Colson '450 does not disclose "a door sensor; door is operative to generate an open signal responsive to the door opening". Appellants respectfully submit that Colson '450 lacks many more of the recited features and relationships. For example, Colson '450 does not use data representative of an authorized user. Colson '450 also does not use data representative of an authorized user stored in a data store. Furthermore, Colson '450 does not disclose the capability of checking whether a user is an authorized user. Colson '450 also does not disclose enabling the input of data corresponding to a medical item, in response to user inputted identification data corresponding to authorized user data. There is no disclosure or suggestion whatsoever in Colson '450 of a data store having each of authorized user data, data representative of medical items, and data corresponding to storage locations where medical items are stored.

Also, Colson '450 does not disclose or suggest the input of indicia corresponding to a medical item through an input device, nor having such input data cause a computer to unlock a door lock. Furthermore, Colson '450 does not disclose passage of a period of time measured

after the output of the signal. Nor does Colson '450 determine the earlier of either sensing the opening of a door or the passage of the time delay period.

The many recited features of which Lavigne lacks in relation to claim 25 have been previously discussed (Issue #2). Appellants' remarks, concerning the alleged anticipation rejection of claim 25 by the Lavigne reference (Issue #2), are herein incorporated by reference. Lavigne cannot overcome the deficiencies of Colson '450 as it also does not disclose or suggest all of the recited features and relationships which are not found in Colson '450.

The Action admits that Colson '450 does not disclose the features and relationships of a door sensor in the manner recited. The Action alleges that Lavigne "discloses a door sensor with the door operative to generate an open signal responsive to the door opening". The Action also alleges that it "would have been obvious to use a sensor to detect the opening of the door as a means of saving power and recording removal of the item as taught by Colson" '450. Appellants respectfully disagree.

Lavigne does not teach or suggest the features and relationships of a door sensor in the manner recited. Nor does Lavigne teach or suggest a computer operative responsive to a sensor sensing opening of a door to change a lock module to a locked condition. Nor does Lavigne teach or suggest the passage of a period of time measured after the output of the signal. Nor does Lavigne determine the earlier of either sensing the opening of a door or the passage of the time delay period. Nor does Lavigne teach or suggest a computer operative responsive to such determination to change a lock module to a locked condition. Hence, Lavigne cannot overcome the deficiencies of Colson '450 as it does not disclose or suggest the recited features and relationships which are not found in Colson '450.

In Lavigne, if the temperature goes out of range, the controller operates a locking solenoid (139) which operates to lock the door (21) to hold it in a closed position (col. 11, lines 37-43; col. 7, lines 24-26). That is, the controller of Lavigne operates the locking solenoid (139) based on sensing temperature conditions, not on sensing whether the door was opened or the passage of a time delay period. Lavigne's door (21) may be opened many times without initiating the locking solenoid (139) (col. 9, lines 7-10; col. 14, lines 34-37; col. 12, lines 15-18).

The Lavigne system senses the opening of a door to record an event in memory. However, neither Colson '450 nor Lavigne discloses or suggests that the sensing of a door opening or that the "passage of a time delay period" causes a lock to be held in a locked condition. Nothing in Colson '450 or Lavigne discloses or suggests that, in response to sensing the opening of a door or the passage of a time delay period, a lock module is changed to a locked condition and held in the locked condition, as is specifically recited in claim 25.

The Office has not made a *prima facie* showing of obviousness. Even if it were somehow possible (which it isn't) for the references to have been combined as alleged, the combination still would not have resulted in the claimed invention. Thus, it would not have been obvious to have combined the references as alleged to have produced the recited invention.

The Claims Are Not Obvious Over Blechl In View of Weinberger

(Issue #11)

Claims 45-50 were rejected under 35 U.S.C. § 103(a) as obvious over Blechl in view of Weinberger. These rejections are respectfully traversed.

Claim 45

Blechl lacks many more of the recited features and relationships than the Examiner admits. The rejection alleges that Blechl teaches "a computer in operative connection with a data store, data store includes user data representative of a plurality of authorized users". The rejection relies on Blechl at col. 4, lines 20-38, which reads:

"Thus, to initiate use of the device 10, a designated individual having access is assigned a magnetic, optical or integrated circuit identification card and a personal identification number (PIN). When the user desires to dispense medication, for example, the user initiates dispensing by inserting an identification card into the card reader 32, upon which the microprocessing means 26 of the present device 10 requests the user to input a personal identification number (PIN). The user's personal identification number (PIN) is then inserted into the microprocessing means 26 via the user interfaced touch screen 30 and, if the personal identification number (PIN) and the identification card are a match, the dispensing can proceed as will be described in more detail below. Alternatively, a finger print or retina scan device can be utilized particularly when extremely sensitive drugs are stored in the device 10".

As can be seen, Blechl does not disclose or suggest a computer in operative connection with a data store that includes data for a plurality of authorized users. The description of Blechl's operation makes clear that Blechl does not include a data store which holds information for a plurality of authorized users. Instead, Blechl has each user insert a conventional ID card which is read by a card reader. The conventional user ID card includes some form of unique identification

data, such as a personal identification number (PIN). Blechl's device then requires the user to input their PIN. The inputted PIN is then conventionally compared to the card's PIN. If the PINs match, then access is allowed (col. 4, lines 23-34; col. 9, lines 13-19). As a result, Blechl makes it very clear that it has no computer connected to a data store holding data for a *plurality* of authorized users.

All the data needed to identify the user is stored on the card. Blechl also suggests that operation control means that is more secure than a PIN may be used in conjunction with the card when extremely sensitive drugs are involved (col. 4, lines 34-36). The more secure means may require that the card data be biometric data, such as a finger print or retina scan (col. 4, lines 34-36); or password, voice identification, or hand print (col. 8, lines 60-68). Regardless of the type of data relied upon for the user identification, the data is stored on the card. Blechl provides no other embodiments for enabling operation of his device other than by using a card with data stored thereon. Blechl's use of a conventional single user ID card teaches away from the recited data store.

Again, Blechl uses a card containing data (such as a user's PIN) for a single user, not a data store holding data for a plurality of authorized users. Blechl simply compares the card data with the data inputted by the user to determine if the system may be operated by that particular user. The inputted data is only compared to the data on the card. An inputted PIN is not compared via a computer to the PINs of a plurality of authorized users stored in a data store. There is no teaching or suggestion in Blechl for comparing inputted user identification data to data store data for a plurality of authorized users.

Weinberger does not disclose or suggest a computer in operative connection with a data store, wherein the data store includes user data representative of a plurality of authorized users. Weinberger is directed to a time scheduled medicine dispenser for a patient not under immediate supervision (e.g., a home-care patient). Weinberger cannot overcome the deficiencies of Blechl as it does not disclose or suggest the recited features which are absent in Blechl. Thus, even if it were somehow possible (which it isn't) for the references to be combined as alleged, the combination still would not have resulted in the claimed invention.

Claim 45 also recites that "the computer is in operative connection with the data store, wherein the data store includes user data representative of a plurality of authorized users, item data representative of a plurality of medical items, and location data representative of storage locations in which the medical items are stored". That is, the recited data store includes data representative of each: (1) a plurality of authorized users; (2) a plurality of medical items; and (3) storage locations in which the medical items are stored. Blechl's card does not include data representative of (1), (2), or (3). It follows that Blechl's card cannot include data representative of (1), (2), and (3). Nor does Blechl disclose or suggest that a "computer is in operative connection with a data store" which includes data representative of (1), (2), and (3).

Weinberger does not disclose or suggest a data store including data representative of a plurality of authorized users, a plurality of medical items, and storage locations in which the medical items are stored. Hence, Weinberger cannot overcome the noted deficiencies of Blechl as it does not disclose or suggest the recited features which are absent in Blechl. Again, even if it were somehow possible (which it isn't) for the references to be combined as alleged, the combination still would not have resulted in the claimed invention.

Claim 45 further recites "a user interface in operative connection with the computer, wherein the interface includes at least one input device"; that a user is capable of "inputting through the at least one input device identification data corresponding to data for an authorized user stored in the data store"; and that a user is capable of inputting "item indicia corresponding to a medical item through the at least one input device". That is, the user is capable of inputting both "identification data" and "item indicia" "through the at least one input device". In Blechl the user identification unit (247) is specifically designed to be separate from the medication input unit (248). For example, note col. 8, lines 45-51, and Figures 12 and 19.

The rejection relies on Blechl at col. 9, lines 36-55 for the recited unlocking feature. However, the relied upon section relates to a drawer, not a door. If a "door" differs from a "drawer", then this is another feature that Blechl does not teach or suggest. Weinberger likewise doesn't teach or suggest the recited unlocking feature. Where does Weinberger even mention a "door"?

Claim 45 additionally recites that responsive to input of data corresponding to one of the plurality of authorized users stored in the data store, the computer of the recited invention enables a user to input item indicia corresponding to a medical item through at least one input device. The Action asserts that Blechl has an input device at col. 4, lines 39-50. This portion of Blechl does not stand for the proposition asserted in the Action. Instead it talks about a mechanic or pharmacist accessing the interior of Blechl's device. It is discussed that such a mechanic or pharmacist can gain access by inputting a matching card and PIN and allowing a door (38) to be opened through a touch screen (30) and operation of a processor. However, there is no disclosure that the touch screen is only enabled to receive inputs in response to prior receipt of a matching

card and PIN. There is certainly no disclosure or suggestion that the mechanic or pharmacist inputs through the touch screen, indicia corresponding to a particular medical item. Indeed, there is no particular medical item that is accessed by opening the door (38). As Blechl does not disclose these features and relationships which are expressly recited in claim 45, the claim is further allowable on this basis.

Weinberger does not disclose or suggest that responsive to input of data corresponding to one of the plurality of authorized users stored in a data store, a computer enables a user to input item indicia corresponding to a medical item through at least one input device. Hence, Weinberger cannot overcome the deficiencies of Blechl as it does not disclose or suggest the recited features which are absent in Blechl. Again, even if it were somehow possible (which it isn't) for the references to be combined as alleged, the combination still would not have resulted in the claimed invention.

In the Action only the features of Blechl are cited as allegedly pertinent to claim 45. No specific features of Weinberger have been cited as applying to claim 45. However, because no 35 U.S.C. § 102 type of rejection was presented against claim 45 based on Blechl, the Action inherently admits that Blechl does not anticipate claim 45. As the Action cites no source of teaching or suggestion to modify the deficient Blechl reference so as to produce the recited claim, the Action does not present a valid 35 U.S.C. § 103(a) rejection.

The Office has not established a *prima facie* showing of obviousness. Neither Blechl nor Weinberger, taken alone or in combination, disclose or suggest the recited features and relationships. Nor would it have been obvious to one having ordinary skill in the art to have combined the references as alleged to have produced the recited invention.

Claim 46

Claim 46 depends from claim 45 and further recites that the lock comprises a visual indicator which provides an indication responsive to at least one signal that the door is enabled to be opened. The Action admits that Blechl does not teach or suggest the recited features. The Action relies on Weinberger at col. 7, lines 13-34 as disclosing the features.

The relied on section of Weinberger does not disclose or suggest a lock comprising a visual indicator, nor a visual indicator providing a visual indication in response to at least one signal from a computer that a door is enabled to be opened. The Action apparently asserts that Weinberger includes a lock module which provides a visual signal that directs a user to a correct door, but no portion of Weinberger is cited for this teaching. Nor does Weinberger disclose or suggest the alleged features. The Office has not established a *prima facie* case of obviousness.

Claim 47

Claim 47 depends from claim 45 and further recites that the lock comprises a door sensor. The door sensor is operative to generate an open signal responsive to an opening of the door. A computer operates responsive to the open signal to change the lock to the locked condition. As a result, when the door is next returned to a closed condition, the door is held closed.

The Action admits that Blechl does not teach or suggest the recited features. The Action relies on Weinberger at col. 13, lines 20-30 as disclosing the features. However, Weinberger does not disclose or suggest the recited features. Weinberger at col. 13, lines 20-30 refers to an opening sensed by a switch to display a messages such as "confirm to continue" and "close cover to continue". The relied upon section of Weinberger is not directed to a lock comprising a door sensor that can generate an open signal responsive to the door opening, to cause the lock to

change to the locked condition. Weinberger does not link sensing a *door* opening to placing a lock in a locked condition.

The Action apparently asserts that Weinberger includes a computer to lock a door responsive to a sensor indicating cover *closure*. However, claim 47 enables changing the lock to a locked condition upon an *opening* (of a door). Locking a *door* upon *opening* differs from the alleged modification of locking a *cover* upon *closing*. Also, if a "door" differs from a "drawer", then this is another feature that is not taught or suggested.

Claim 47 recites that "the door sensor is operative to generate an open signal responsive to opening the door, and wherein the computer is operative responsive to the open signal to change the lock to the locked condition, wherein when the door is next returned to a closed condition the door is held therein".

In Blechl, the user manually closes the drawer. The "latch mechanism *secures* the drawer and communicates to the microprocessing means that the drawer *has* been closed" (col. 9, lines 56-64). That is, at best, a closed drawer signal is generated, not an *open* door signal as recited.

Blechl's computer is not operative responsive to an *open* signal. Nor does it appear that Blechl's computer is even operative responsive to a closed signal. It follows that Blechl's computer is not responsive to an open signal to change a lock to a locked condition. Contrarily, in Blechl the microprocessor is notified only after the drawer *has* been closed and apparently after the drawer has already been locked (secured). Hence, there is no need for the computer to change the lock to the locked condition.

Claim 47 further recites that the computer changes the lock to the locked condition so that "when the door is next returned to a closed condition the door is held therein". That is, the

computer places the lock in the locked condition prior to the door being returned to the closed condition. In Blechl, a "latch mechanism *secures* the drawer and communicates to the microprocessing means that the drawer *has* been closed" (col. 9, lines 56-64). That is, in Blechl's system the drawer is first closed and secured, then the microprocessing means is notified. Blechl does not teach or suggest, nor does Blechl appear capable of, the microprocessing means initiating a locked condition prior to a door being closed. Nor does Blechl teach or suggest the microprocessing means initiating a locked condition prior to a door being closed in response to the door being open.

The Action states that "It would have been obvious for Blechl to have the computer to lock the door responsive to a sensor indicating door *closure* because locking the door can reduce unauthorized access as taught by Weinberger". It is noted that the Action refers to "a sensor indicating door *closure*". However, claim 47 clearly recites that the "door sensor is operative to generate an open signal responsive to *opening* the door". It is respectfully submitted that the Action's starting basis for obviousness is completely opposite to the recited claim language. Thus, even if the references were combined in the manner alleged, the combination would still fall short of the claimed invention. Again the Office takes the position that there is no distinction between a "door" and a "drawer", showing the validity of Appellants' reduction to practice, as established in their Declaration, of the subject matter of claims 24 and 45 prior to March 7, 1994.

As noted above, Blechl lacks many of the recited features and relationships. Weinberger also does not disclose or suggest that a "door sensor is operative to generate an open signal responsive to opening the door", nor that a "computer is operative responsive to the open signal to change the lock to the locked condition", nor that "when the door is next returned to a closed

condition the door is held therein". No portion of Weinberger is cited for these recited features and relationships. Nor is it seen where Weinberger discloses such alleged features and relationships. Further, no teaching or suggestion for combining features of Weinberger with features of Blechl is presented in the Action. Weinberger cannot overcome the deficiencies of Blechl as it does not disclose or suggest the recited features and relationships which are absent in Blechl. The Office has not established a *prima facie* showing of obviousness.

Claim 48

The Action does not address claim 48. Nevertheless, for reasons already discussed, Blechl does not determine whether inputted data corresponds in a data store to an authorized user, especially where the data store stores each of: "item data" representative of each of a plurality of medical items; "location data" corresponding to each of a plurality of storage locations in which the plurality of medical items are stored; and "user identifier" data corresponding to a plurality of user identifiers, wherein each user identifier is representative of a different authorized user. Blechl also does not teach that a computer, responsive to receiving input (from an authorized user determined via the data store) that corresponds to a particular medical item, causes unlocking of a lock to permit access to a storage location where the particular medical item is located. Blechl teaches neither the recited features nor the recited relationships.

For reasons already discussed, Weinberger cannot overcome the deficiencies of Blechl as it does not disclose or suggest the recited features and relationships which are absent in Blechl. Nor is there any indication that Weinberger is being relied upon in the rejection. The Office has not established a *prima facie* case of obviousness.

Claim 49

Claim 49 depends from claim 48. For reasons already discussed, Blechl does not teach or suggest a door being unlocked by a computer in response to input corresponding to a particular medical item. Again the rejection establishes the Office's position that a "door" and a "drawer" are effectively the same. However, if the Board decides that a "door" differs from a "drawer", then Blechl is even further removed from the recited features. For reasons already discussed, Weinberger cannot overcome the deficiencies of Blechl as it does not disclose or suggest the recited features and relationships which are absent in Blechl. Nor is there any indication that Weinberger is being relied upon in the rejection of claim 48. The Office has not established a *prima facie* case of obviousness.

Claim 50

For reasons already discussed, neither of the references teaches or suggests a computer that, responsive to receiving input (from an authorized user determined via a data store) that corresponds to a particular medical item, causes unlocking of a drawer to permit access to a storage location where the particular medical item is located. The Office has not established a *prima facie* case of obviousness.

The Claims Are Not Obvious Over Lavigne In View Of Engleson

(Issue #12)

Claims 16-20 and 34-35 were rejected under 35 U.S.C. § 103(a) as obvious over Lavigne in view of Engleson. The Action admits that Lavigne does not teach or suggest the features and relationships recited in the claims 16-20 and 34-35. Appellants below show that Engleson also does not teach or suggest the recited features and relationships.

Claim 16

Claim 16 depends from claim 1. Engleson cannot alleviate the deficiencies of Lavigne as it does not teach or suggest the recited features and relationships not found in Lavigne. Neither of the references, taken alone or in combination, teach or suggest the recited invention.

The Action relies on Engleson's barcode reader (90), which is connected to a bedside CPU (80) (col. 6, lines 14-17). The Action is silent as to how Engleson's bedside barcode reader (90) enables a user to input indicia corresponding to a medical item therethrough such that the CPU (80) is responsive to the input to output a signal changing a refrigerator door lock to an unlocked condition. Where does Engleson discuss the relationship between a refrigerator door and a lock module attached to the refrigerator? The Office has not established a *prima facie* case of obviousness. It would not have been obvious to one having ordinary skill in the art to have combined the references as alleged to have produced the recited invention.

Claim 17

Claim 17 depends from claim 16/1. Engleson does not teach or suggest a refrigerator with machine readable indicia thereon, especially at the relied upon col. 6, lines 14-25 which reads:

"Each bedside CPU 80 can be connected through an appropriate interface to a variety of peripheral equipment. For example, a barcode reader 90 capable of reading barcodes on a patient's wristband or medication container; an infusion pump 92 for delivering medication to the patient in a predetermined, controlled manner; or various sensors 94 that can automatically monitor a patient's vital signs and send signals representative of these vital signs to the computer through an appropriate interface for storage and later retrieval by a selected software application to provide a graphic display of the patient's vital signs during the course of treatment".

The Office has not established a *prima facie* showing of obviousness. It follows that even if it were somehow possible (which it isn't) for the references to be combined as alleged, the combination would not have resulted in the claimed invention.

Claim 18

Claim 18 depends from claim 16/1. Engleson does not teach or suggest a report having machine readable indicia thereon. The relied upon section (col. 12, lines 45-65) of Engleson is directed to a label. One having ordinary skill in the art would distinguish a report from a label. Even Engleson distinguishes a report from a label. For example, note Engleson's mention of a report at col. 5, lines 26-33; col. 2, lines 28-31; and col. 4, lines 50-59. Again, the Office has not established a *prima facie* showing of obviousness.

Claim 19

Claim 19 depends from claim 18/16/1. Engleson does not teach or suggest a computer operative to cause a printer to print a report having machine readable indicia thereon, where item indicia can be input by reading the machine readable indicia on the report, and where a computer is responsive to the input of the item indicia to output a signal changing a lock module to an

unlocked condition. Thus, Engleson cannot alleviate the deficiencies of Lavigne as it does not teach or suggest the recited features and relationships not found in Lavigne.

Claim 20

Claim 20 depends from claim 16/1. Neither of the references, taken alone or in combination, teach or suggest an interior area of a refrigerator having machine readable indicia. Again, note Engleson at the relied upon col. 6, lines 14-25. Nor do the references teach or suggest an ability to include in a data store, responsive to reading the indicia, data representative of the taking of the medical item from the interior area of the refrigerator. The Office has not established a *prima facie* showing of obviousness.

Claim 34

Claim 34 depends from claim 27. The references don't teach or suggest labeling a refrigerator with machine readable indicia corresponding to the type of medical item stored in the interior area of the refrigerator. Again, note Engleson at the relied upon col. 6, lines 14-25. The Office has not established a *prima facie* case of obviousness.

Claim 35

Claim 35 depends from claim 34/27. Nor do the references teach or suggest labeling a refrigerator with a bar code, and reading from the bar code the type of medical item stored in the interior area of a refrigerator. The Office has not established a *prima facie* case of obviousness.

The Claims Are Not Obvious Over Colson '450 in view of Iwamoto

(Issue #13)

Claims 4-8 and 40 were rejected under 35 U.S.C. § 103(a) as obvious over Colson '450 in view of Iwamoto. The Action admits that Colson '450 does not teach or suggest the features and relationships recited in the claims 4-8 and 40. Appellants below show that Iwamoto also does not teach or suggest the recited features and relationships.

Claim 4

Claim 4 depends from claim 1. Appellants' previous remarks (Issue #3) against the anticipation rejection of claim 4 based on the Colson '450 reference alone are herein incorporated by reference. Iwamoto cannot alleviate the admitted deficiencies in Colson '450 as it does not teach or suggest the recited features and relationships not found in Colson '450.

Iwamoto does not teach or suggest a refrigerator lock module which can be both manually unlocked (claim 4) and unlocked responsive to a computer signal (claim 1). Nor is Colson '450 directed to use of a computer to output an unlocking signal. It would not have been obvious to one having ordinary skill in the art to have combined the references as alleged to have produced the recited invention.

Claim 5

Claim 5 depends from claim 4/1. Neither of the references, taken alone or in combination, teach or suggest a system for providing medical items having the recited relationships of a refrigerator lock module, a movable lever, a solenoid, a catch, a pawl, where the catch is engageable to hold the pawl, and where the pawl is operatively engageable with the

refrigerator door. Thus, even if it were somehow possible for the references to be combined as alleged, the combination still would not have resulted in the claimed invention.

Claim 6

Claim 6 depends from claim 5/4/1. As previously discussed, Iwamoto does not teach or suggest the recited features of claim 5/4/1 that are not found in Colson '450. It follows that the combined references cannot produce the recited solenoid, lever, and manual unlocking mechanism arrangement of claim 6.

Claim 7

Claim 7 depends from claim 5/4/1. As previously discussed, Iwamoto does not teach or suggest the recited features of claim 5/4/1 that are not found in Colson '450. It follows that the combined references cannot produce the recited tapered step feature of claim 7.

Claim 8

Claim 8 depends from claim 5/4/1. The Action is silent as to what element in Iwamoto constitutes the recited manual unlocking mechanism cylinder, and the projection rotatable in engagement with the cylinder. Nor does Iwamoto teach or suggest the recited features. It follows that the combined references would not have resulted in the recited invention of claim 8.

Claim 40

Claim 40 depends from claim 39/27. Iwamoto does not teach or suggest engaging a pivot lever on an opposite sides to move the lever in the same direction, in the manner recited. The references, taken alone or in combination, do not teach or suggest the recited features and relationships.

Claim 23 Is Not Obvious Over Colson '450 in view of Warren

(Issue #14)

Claim 23

Claim 23 depends from claim 1. The Action admits that Colson '450 does not teach or suggest the recited features and relationships. Appellants have previously addressed in their remarks in Issue #3 (regarding the rejections of claims 12 and 24), the lack of any teaching or suggestion in Colson '450 of a door lock module attached to an exterior surface of a refrigerator.

Warren also does not teach or suggest a door lock module attached to an exterior surface of a refrigerator. At best, Warren is directed to a file cabinet, not a refrigerated system for providing medical items. The Office has not established a *prima facie* showing of obviousness. It follows that it would not have been obvious to one having ordinary skill in the art to have attached a door lock module including a retrofit assembly to an exterior surface of a refrigerator in the manner recited to have produced the recited invention.

The Claims Are Not Obvious Over Colson '450 in view of Holmes

(Issue #15)

Claims 9, 16-17, 20, 22, and 34-35 were rejected under 35 U.S.C. § 103(a) as obvious over Colson '450 in view of Holmes. The Action admits that Colson '450 does not teach or suggest the features and relationships recited in the claims. Appellants below show that Holmes also does not teach or suggest the recited features and relationships.

Claim 9

Claim 9 depends from claim 1. The Action (at page 12, last sentence; Issue #10) admits that Colson '450 does not teach or suggest "a door sensor; door is operative to generate an open signal responsive to the door opening". That is, the Action admits that Colson '450 does not teach or suggest the recited refrigerator door sensor, especially to cause a storing of data representative of the door opening.

The rejection relies on Holmes at col. 8, lines 12-15, which reads:

"Optionally, drawer 14 may include a sensor 84 which is employed to detect when drawer 14 is withdrawn from cabinet 12. Sensor 84 is connected to PC "board" 74 by a line 85".

Where does this relies upon section of Holmes teach or suggest a sensor that can generate an open signal responsive to opening a refrigerator *door* to cause the storing of data representative of the opening? If the Board should decide a "door" differs from a "drawer" (which it should not and which is contrary to the Office's current position), then Holmes is even further removed from the recited features. The Office has not established a *prima facie* case of obviousness.

Claim 16

Claim 16 depends from claim 1. Neither of the references, taken alone or in combination, teach or suggest the ability to input medical item indicia through a reading device of a medical item system to provide medical items in the manner recited.

Claim 17

Claim 17 depends from claim 16/1. Neither of the references, taken alone or in combination, teach or suggest a refrigerator having machine readable indicia thereon. The relied upon section (col. 6, lines 19-25) of Holmes reads:

"optionally, cabinet 12 may further include a mag or bar code reader 25 which is connected to the processor. Reader 25 may be provided to allow a user or a patient to be conveniently identified by swiping an appropriate ID card through reader 25. Reader 25 may also be employed to read an identification device associated with the drawers".

That is, the relied upon section of Holmes refers to a card reader, not machine readable indicia on a refrigerator. The Office has not established a *prima facie* showing of obviousness.

Claim 20

Claim 20 depends from claim 16/1. The relied upon section (col. 6, lines 19-25) of Holmes also does not teach or suggest an interior area of a refrigerator having machine readable indicia therein, such that a user is enabled to read the machine readable indicia after opening the refrigerator door. Holmes also does not teach or suggest a computer that is operative responsive to the indicia reading to include data in a data store representative of taking a medical item from the interior area of the refrigerator. The Office has not established a *prima facie* showing of obviousness. Nor would any combination of the references have produced the recited invention.

Claim 22

Claim 22 depends from claim 9/1. Neither of the references, taken alone or in combination, teach or suggest the ability to store data representative of a refrigerator door not being opened, responsive to a refrigerator lock module being returned to the locked condition after the door was not opened during a period of time. The Office has not established a *prima facie* showing of obviousness.

Claim 34

Claim 34 depends from claim 27. The references don't teach or suggest labeling a refrigerator with machine readable indicia corresponding to the type of medical item stored in the interior area of the refrigerator. Again, note above reproduced relied upon section (col. 6, lines 19-25) of Holmes. The Office has not established a *prima facie* case of obviousness.

Claim 35

Claim 35 depends from claim 34/27. Nor do the references teach or suggest labeling a refrigerator with a bar code, and reading from the bar code the type of medical item stored in the interior area of a refrigerator. Again, note above reproduced relied upon section (col. 6, lines 19-25) of Holmes. The Office has not established a *prima facie* case of obviousness.

The Claims Are Not Obvious Over Lavigne in view of Holmes

(Issue #16)

Claims 9, 16-17, 20, 22, 34-35, and 42-44 were rejected under 35 U.S.C. § 103(a) as obvious over Lavigne in view of Holmes. The Action admits that Lavigne does not teach or suggest the features and relationships recited in these claims 4-8 Appellants below show that Holmes also does not teach or suggest the recited features and relationships.

Claims 9, 16-17, 20, 22, and 34-35

Appellants' Issue #15 remarks with regard to claims 9, 16-17, 20, 22, and 34-35 are herein incorporated by reference. As previously discussed (Issue #15), Holmes does not teach or suggest the features and relationships recited in claims 9, 16-17, 20, 22, and 34-35. It follows that it would not have been obvious (or possible) to have combined Holmes with Lavigne to have produced the recited subject matter of claims 9, 16-17, 20, 22, and 34-35.

Claim 42

Method claim 42 depends from claim 27. As best understood, the Action does not address the subject matter of claim 42. Regardless, as previously discussed, Lavigne does not teach or suggest determining (with a computer and data store) whether inputted user data corresponds to one of a plural authorized users. Holmes cannot alleviate this deficiency in Lavigne as it also does not teach or suggest the recited feature.

Furthermore, neither of the references, taken alone or in combination, teach or suggest generating a signal with a computer, responsive to not sensing opening of a refrigerator door after a time period, where the signal is operative to cause a lock module to hold the door in a closed position. The Office has not established a *prima facie* showing of obviousness.

Claim 43

Method claim 43 depends from claim 42/27. As best understood, the Action does not address the subject matter of claim 43. That is, the Action is silent as to where Holmes teaches or suggests the recited features and relationships of claim 43. Nevertheless, neither of the references, taken alone or in combination, teach or suggest storing in a data store data representative of a door being able to be opened by an authorized user but not being opened.

Claim 44

The Action is also silent as to where the references teach or suggest the recited features and relationships of independent claim 44. As previously discussed (Issue #2 regarding claim 44), Lavigne does not teach or suggest the recited features and relationships of claim 44. As previously discussed, nothing in Lavigne teaches or suggests controlling a housing structure lock to selectively open in response to an inputted medical item type corresponding to a medical item in the housing structure. As previously discussed, Lavigne makes amply clear that the door (21) of his medication carrier is always unlocked except in circumstances when an out of range temperature condition has been sensed, in which case the door will *lock* because a temperature violation (which could have damaged the medications) has occurred (see col. 11, lines 37-43).

Holmes cannot alleviate the deficiencies of Lavigne as it does not teach or suggest the recited features and relationships not found in Lavigne. Holmes does not teach or suggest controlling a housing structure lock to selectively open in response to an inputted medical item type corresponding to a medical item in the housing structure. It follows that it would not have been obvious to one having ordinary skill in the art to have combined the references as alleged to have produced the recited invention of claim 44.

The Claims Are Not Obvious Over Halvorson in view of McDonald

(Issue #17)

Claims 45 and 48-50 were rejected under 35 U.S.C. § 103(a) as obvious over Halvorson in view of McDonald.

Claim 45

The Action alleges that Halvorson teaches the recited features and relationships of claim 45. The Action relies on Halvorson at sections col. 2, lines 37-61 and col. 3, line 47 to col. 4, line 38, which read:

"The dispensing system of the present invention solves all of the above noted problems of medication distribution in health care institutions. Medication errors due to mistakes in transcription are eliminated by allowing all orders to be inserted by pharmacists. Omission errors are eliminated by the dispensing cabinets at each dispensing station. Staffing needs are reduced by controlling all dispensing from a central pharmacy and by allowing pharmacy control from remote stations. Added to these advantages are automatic inventory control, automatic billing, automatic patient profiles, automatic medication administration reports, automatic hourly patient medication requirements report, automatic daily evaluation of medication due to discontinue, automatic drug-interaction and allergy warnings.

Other advantages are the elimination of narcotic counts, real-time inventory evaluation, the ability to customize the hours and days to administer medication on a routine basis, the ability to limit the minimum and maximum times between doses on as needed medications, the ability to suspend all or specific orders for a patient for a variety of conditions, as well as the ability generate numerous administrative reports on demand.

The dispensers 32 of the preferred system have a software controllable, electrical interface that may receive data from the central computer 10. Logic circuits in the interface evaluate the data sent by the computer 10. This data may be categorized as; multiplexer instructions; dispenser

operation commands; medication selection; data to be video displayed and/or printed. The interface contains a multiplexer that routes the data received to either the dispenser operations logic interpreter, the medication selector logic or to the external peripherals. The dispenser operator interpreter causes the dispenser to report its status to the computer 10, lock and unlock the access doors 40 and to raise or lower the elevator if it is so equipped, etc. The medication selector logic causes the appropriate electrical device, such as a motor or solenoid to release a dose of a particular medication.

The interface also has the appropriate logic circuits to monitor various status conditions and to send this information to the computer. These status indicators may include, but not be limited to, such things as stocking access doors open/closed, medication access doors open/closed, elevator position, power failure, polling enabled/disabled, dispenser enabled/disabled & dispenser active/idle. The interface can send status messages to the computer 10 if solicited by the computer 10, if unsolicited (yet sensed by the interface), or during polling.

The polling messages are automatically sent to the computer 10 several times per minute. The primary purpose being to monitor the dispenser's operational condition. The software causes the computer 10 to keep track of the elapsed time between pollings and if it exceeds a prescribed length of time, the system will first attempt to resolve the problem itself. If this is not successful, it will notify the appropriate operational personnel of the problem. These problems will include but will not be limited to; loss of power to the dispenser, failure of communication lines (including telephone lines) between the computer 10 and the dispenser 32 or interface failure. In most instances, the computer 10 will rectify the problem once it has been made aware of it by the interface.

Reports that are created automatically or that are requested to be sent to a terminal, are held temporarily in spooling until the terminal is known to be in the idle condition at which time, the report is printed automatically.

The preferred dispensing station will have a dispenser 32 which contains a plurality of medications that may be automatically dispensed to authorized personnel on demand. No medications are dispensed without first being authorized by a physician.

In general, all patient orders can be divided into the categories of being Routine or PRN. Routine medications are given on a periodic basis and at specified times. PRN medications may be given as the patient requires them, as long as certain limits on dosage and time interval are met".

As can be seen, Halvorson at the relied upon sections does not teach or suggest the recited features and relationships. Halvorson at best teaches that the "preferred dispensing station will have a dispenser 32 which contains a plurality of medications that may be automatically dispensed to authorized personnel on demand" (col. 4, lines 27-32). That is, a nurse can request (demand) and then receive the medication.

McDonald at the relied upon section (col. 2, lines 46-61) reads:

"A nurse using the system enters an authorized access code in combination with patient information utilizing a keyboard or touch screen. Upon entry of such information the drawer containing the medication prescribed for that patient or the drawer containing on demand medication requested by the patient is unlocked. The drawers are spring loaded so that once unlocked the appropriate drawer will move outward from the housing. The nurse removes and uses the necessary items from the drawer and the unlocked drawer is reclosed and relocked. The processing unit will generate a detailed record specifying the time and date the patient drawer opens, the pharmaceutical items removed, and identification of the nurse or other person accessing the drawer".

As can be seen, a nurse using McDonald's system enters an authorized access code. The system of McDonald is similar to a conventional personal computer that requires only a single code or password to provide access to plural users. In McDonald the same single code is used by

all nurses. McDonald does not teach or suggest the recited relationships among authorized user, data store of plural authorized users data, computer, medical item indicia, and door unlocking.

Neither reference teaches or suggests a data store including user data representative of a plurality of authorized users. Neither reference inputs authorized user identification data, or compares an inputted user identification to a plurality of authorized users. Neither of the references teach or suggest that responsive to input of data corresponding to one of a plurality of authorized users stored in a data store, a computer enables a user to input medical item indicia corresponding to a medical item through an input device, and that a computer is operative responsive to the indicia input to cause a lock to be unlocked.

Where do the combined references teach or suggest a data store including user data representative of a *plurality* of authorized users? Where do the combined references teach or suggest that after a user's inputted identification data corresponds to one of many authorized users, a computer enables the user to input medical item indicia to cause the unlocking of a door lock? Where do the references teach or suggest the ability to unlock a lock responsive to the input of item indicia by a matched authorized user? In McDonald, unlocking of the drawer lock (40) is related to seeing the patient's (not an authorized user's) identification. The Office has not established a *prima facie* showing of obviousness.

McDonald is directed to drawers (10). Thus the Office contends a "door" and a "drawer" are effectively the same, establishing that Appellants are entitled to a reduction to practice date for at least claims 24 and 45 prior to March 7, 1994. Conversely, if the Board decides that a "door" differs from a "drawer", then McDonald is even further removed from the recited features.

Furthermore, the Action's statement about changing McDonald's "lock module (40) to the *locked condition*", and modifying Halvorson in such manner, is moot because claim 45 is directed to changing the lock to an *unlocked condition*. That is, even if it were somehow possible to have modified Halvorson "to have the computer lock the door or a respective drawer" in the manner alleged by the Office, it still would not have resulted in the actual recited language (invention) of claim 45.

Claim 48

The Action does not address claim 48. Nevertheless, Halvorson does not determine whether inputted data corresponds in a data store to an authorized user, especially where the data store stores each of: item data" representative of each of a plurality of medical items; "location data" corresponding to each of a plurality of storage locations in which the plurality of medical items are stored; and "user identifier" data corresponding to a plurality of user identifiers, wherein each user identifier is representative of a different authorized user. Halvorson also does not teach that a computer, responsive to receiving input (from an authorized user determined via the data store) that corresponds to a particular medical item, causes unlocking of a lock to permit access to a storage location where the particular medical item is located. Halvorson teaches neither the recited features nor the recited relationships.

McDonald cannot overcome the deficiencies of Halvorson as it does not disclose or suggest the recited features and relationships which are absent in Halvorson. Appellants have already shown that McDonald at the relied upon section (col. 2, lines 46-61; reproduced above) does not teach or suggest the recited features and relationships. The Office has not established a *prima facie* case of obviousness.

Claim 49

The Action does not address claim 49. Nor does the Action address whether the relied upon McDonald teaches a "door" or a "drawer". The Office considers them the same (which means Appellants' Declaration establishes reduction to practice prior to March 7, 1994 for at least claims 24 and 45). Claim 49 is directed to a housing door. However, as no basis for rejection is presented in the Action, the Office has not presented a *prima facie* case of obviousness.

Claim 50

The relied upon McDonald does not teach or suggest that a computer, responsive to receiving input that corresponds to a particular medical item, unlocks a drawer lock to permit access to a storage location where the particular medical item is located. In McDonald, each patient has their own assigned drawer (col. 4, lines 36-39 and 63-65). Input of patient ID information causes the appropriate patient drawer to open. There is no teaching or suggestion whatsoever in McDonald that a nurse provides a particular medical item input to cause a drawer to open. At best, a nurse enters an access code in combination with patient information.

McDonald's nursing center is programmed so that in memory (21) there will be an identification (ID) of the patients to which each patient drawer corresponds. A patient drawer holds medications that were specifically prescribed for that specific patient, and are to be administered according to a time schedule. The patient may also receive other assigned non-prescribed medications, such as aspirin or pain medicine, from an on demand drawer (i.e., a non patient specific drawer). Upon entry of access code/patient ID information, the drawer (or drawers) holding the items previously assigned for the specific patient is unlocked. That is, input

of a patient ID causes unlocking of a patient drawer holding that patient's previously prescribed medication and/or unlocking of a drawer holding that patient's previously requested but non-prescribed medication. Drawer opening is not based on a particular medical item input. The Office cannot add to McDonald what McDonald does not teach. A *prima facie* case of obviousness has not been established.

Further evidence that McDonald does not teach or suggest the recited features is shown in Weinberger. Weinberger discusses use of a conventional on-demand drawer. When the user needs to take a demand pill, he presses a demand key (43) and then a dispense key (40), which causes the on-demand drawer (21) to open. On-demand drawer opening is not based on a particular medical item input. Furthermore, any requirement of a particular medical item input would appear to defeat the purpose of an on-demand drawer.

The Claims Are Not Obvious Over Halvorson in view of Weinberger

(Issue #18)

Claims 45-50 were rejected under 35 U.S.C. § 103(a) as obvious over Halvorson in view of Weinberger.

The Action admits that Halvorson does not teach or suggest the features and relationships recited in the claims. Additionally, Appellants have already explained (in Issue #17) in detail why Halvorson does not teach or suggest the features and relationships recited in claims 45 and 48-50. Thus, for sake of brevity, Appellants' Issue #17 remarks with regard to Halvorson and claims 45 and 48-50 are herein incorporated by reference.

As previously discussed (Issue #11), Weinberger also does not teach or suggest the recited features and relationships of claims 45 and 48-50. For reasons of brevity, Appellants' Issue #11 remarks with regard to Weinberger and claims 45 and 48-50 are likewise herein incorporated by reference.

Claim 45

Weinberger cannot alleviate the many deficiencies of Halvorson as it does not teach or suggest the recited features and relationships not found in Halvorson. Weinberger is directed to a time scheduled medicine dispenser for a patient not under immediate supervision (e.g., a home-care patient).

Weinberger at best is directed to a "drawer". The Office thus considers that a "drawer" includes a "door", proving that Appellants are entitled to their claimed March 7, 1994 reduction to practice for at least claims 24 and 45. Weinberger does not mention a "door". If the Board

should decide a "door" differs from a "drawer", then Weinberger is even further removed from the recited features.

Weinberger does not teach or suggest a data store including user data representative of a plurality of authorized users. Weinberger does not teach or suggest that responsive to input of data corresponding to one of the plurality of authorized users stored in a data store, a computer enables a user to input item indicia corresponding to a medical item through at least one input device. The cited sections of Weinberger are not pertinent to that for which they are relied upon. The Office has not established a *prima facie* showing of obviousness.

Neither of the references, taken alone or in combination, teach or suggest the recited features and relationships. Thus, even if it were somehow possible (which it isn't) for the references to be combined as alleged, the combination still would not have resulted in the claimed invention. It follows that it would not have been obvious to one skilled in the art to have combined the references as alleged to have produced the recited invention of claim 45.

Claim 46

Claim 46 depends from claim 45 and further recites that the *lock* comprises a visual indicator which provides an indication responsive to at least one signal that the door is enabled to be opened. The Action relies on Weinberger for teaching a lock comprising a visual indicator. However, the relied upon section (col. 7, lines 13-34) of Weinberger does not appear pertinent to the recited subject matter.

The relied upon section relates to loading a drawer (20), not to providing a visual indication (via a lock's visual indicator) that a door is enabled to be opened. At best, each drawer compartment has a loading light (33). Weinberger does not teach or suggest a door lock

comprising a visual indicator. Weinberger likewise doesn't teach or suggest the recited lock, door, and visual indicator relationships. The Office has not established a *prima facie* showing of obviousness.

The citation of Weinberger's "drawer" as corresponding to the Appellants' recited "door" is another example of how Appellants' Declaration establishes a reduction to practice of a system that would include a "door" prior to March 7, 1994. This prior reduction to practice applies to at least claims 24 and 45.

Claim 47

Claim 47 depends from claim 45 and further recites that the *lock* comprises a door sensor. The door sensor is operative to generate an open signal in response to opening of the door. A computer operates responsive to the open signal to change the lock to the locked condition. As a result, when the door is returned to a closed condition, the door is held closed.

The Action relies on Weinberger for teaching the recited door sensor and relationships. However, Weinberger does not teach or suggest the recited door sensor arrangement, especially at relied on col. 13, lines 20-30.

As previously discussed, Weinberger is directed to a "drawer", and does not even mention a "door", thus showing the Office considers them to be the same thing. This provides Appellants' March 7, 1994 reduction to practice.

Neither of the references teach or suggest a computer operative responsive to an open door signal to change a door lock to a locked condition. Neither of the references teach or suggest that in response to sensing the opening of a door, the door's lock condition is changed so that the door will be locked the next time it is closed.

The Office has not established a *prima facie* showing of obviousness. Nor would it have been obvious to have combined the references as alleged to have produced the recited invention.

Claim 48

For reasons already discussed, Weinberger cannot overcome the deficiencies of Halvorson as it does not disclose or suggest the recited features and relationships which are absent in Blechl. Nor is there any indication that Weinberger is being relied upon in the rejection of claim 48. Nevertheless, Weinberger does not determine whether inputted data corresponds in a data store to an authorized user, especially where the data store stores each of: item data" representative of each of a plurality of medical items; "location data" corresponding to each of a plurality of storage locations in which the plurality of medical items are stored; and "user identifier" data corresponding to a plurality of user identifiers, wherein each user identifier is representative of a different authorized user. Weinberger also does not teach that a computer, responsive to receiving input (from an authorized user determined via the data store) that corresponds to a particular medical item, causes unlocking of a lock to permit access to a storage location where the particular medical item is located. The Office has not established a *prima facie* case of obviousness.

Claim 49

Claim 49 depends from claim 48. Weinberger does not teach or suggest a door being unlocked by a computer in response to input corresponding to a particular medical item. As previously discussed, Weinberger is directed to a "drawer", which the Office holds is the same or includes the recited "door". However, if the Board decides a "door" differs from a "drawer", then

Weinberger is even further removed from the recited features. The Office has not established a *prima facie* case of obviousness.

Claim 50

Weinberger also does not teach or suggest a computer that, responsive to receiving input (from an authorized user determined via a data store) corresponding to a particular medical item, causes unlocking of a drawer to permit access to a storage location where the particular medical item is located. At best, a drawer in Weinberger opens in response to the pressing of the dispense key (40), in response to a particular medical item input. The Office has not established a *prima facie* case of obviousness.

The Claims Are Not Obvious Over Colson '450 in view of Gombrich

(Issue #19)

Claims 16-20 and 34-35 were rejected under 35 U.S.C. § 103(a) as obvious over Colson '450 in view of Gombrich.

The Action admits that Colson '450 does not teach or suggest the features and relationships recited in claims 16-20 and 34-35. Additionally, Appellants have already explained (in Issue #15) in detail why Colson '450 does not teach or suggest the features and relationships recited in claims 16-17 and 34-35. Thus, for sake of brevity, Appellants' Issue #15 remarks with regard to Colson '450 and claims 16-17 and 34-35 are herein incorporated by reference.

Claim 16

Claim 16 depends from claim 1. Gombrich cannot alleviate the previously discussed (e.g., claim 1) deficiencies of Colson '450, let alone the further ability to input item indicia through a reading device to provide medical items in the manner recited. Where does the Gombrich even mention a refrigerator? The Office has not established a *prima facie* case of obviousness.

Claim 17

Claim 17 depends from claim 16/1. Gombrich does not teach or suggest a refrigerator having machine readable indicia thereon. The relied upon section (col. 8, lines 4-30) of Gombrich does not refer to machine readable indicia or to a refrigerator. Where does the Gombrich even mention a refrigerator? Gombrich does not teach or suggest the features for which it was relied upon. The Office has not established a *prima facie* showing of obviousness.

Claim 18

Claim 18 depends from claim 16/1. Neither of the references, taken alone or in combination, teach or suggest reading machine readable indicia on a report to cause the input of medical item indicia resulting in the unlocking of a door, in the manner recited. A *prima facie* case of obviousness has not been established.

Claim 19

Claim 19 depends from claim 18/16/1. Neither of the references, taken alone or in combination, teach or suggest a computer operative to cause a printer to print a report having machine readable indicia thereon, where item indicia can be input by reading the machine readable indicia on the report, and where a computer is responsive to the input of the item indicia to output a signal changing a lock module to an unlocked condition. A *prima facie* case of obviousness has not been established.

Claim 20

Claim 20 depends from claim 16/1. Neither of the references, taken alone or in combination, teach or suggest an interior area of a refrigerator having machine readable indicia therein, such that a user is enabled to read the machine readable indicia after opening the refrigerator door, and a computer is operative responsive to the interior indicia reading to store data representative of taking a medical item from the interior area. Gombrich does not teach or suggest the features for which it was relied upon. A *prima facie* case of obviousness has not been established. Nor would it have been obvious to one having ordinary skill in the art to have combined the references as alleged to have produced the recited invention.

Claim 34

Claim 34 depends from claim 27. The references don't teach or suggest labeling a refrigerator with machine readable indicia corresponding to the type of medical item stored in the interior area of the refrigerator. The Office has not established a *prima facie* case of obviousness.

Claim 35

Claim 35 depends from claim 34/27. Nor do the references teach or suggest labeling a refrigerator with a bar code, and reading from the bar code the type of medical item stored in the interior area of a refrigerator. The Office has not established a *prima facie* case of obviousness.

The Claims Are Not Obvious Over Lavigne in view of Iwamoto

(Issue #20)

Claims 4-11 and 21 were rejected under 35 U.S.C. § 103(a) as obvious over Lavigne in view of Iwamoto. The Action admits that Lavigne does not teach or suggest the features and relationships recited in claims 4-11 and 21.

Claim 4

Claim 4 depends from claim 1. Iwamoto cannot alleviate the deficiencies of Lavigne as it does not teach or suggest the recited features and relationships not found in Lavigne. Neither of the references, taken alone or in combination, teach or suggest a refrigerator lock module which can be both manually unlocked (claim 4) and unlocked responsive to a computer signal (claim 1).

Claim 5

Claim 5 depends from claim 4/1. Neither of the references, taken alone or in combination, teach or suggest a system for providing medical items having the recited relationships of a refrigerator lock module, a movable lever, a solenoid, a catch, a pawl, where the catch is engageable to hold the pawl, and where the pawl is operatively engageable with the refrigerator door. Thus, even if it were somehow possible for the references to be combined as alleged, the combination still would not have resulted in the claimed invention.

Claim 6

Claim 6 depends from claim 5/4/1. As previously discussed, Iwamoto does not teach or suggest the recited features of claim 5/4/1 that are not found in Lavigne. It follows that the combined references cannot produce the recited solenoid, lever, and manual unlocking mechanism arrangement of claim 6.

Claim 7

Claim 7 depends from claim 5/4/1. As previously discussed, Iwamoto does not teach or suggest the recited features of claim 5/4/1 that are not found in Lavigne. It follows that the combined references cannot produce the recited tapered step feature of claim 7.

Claim 8

Claim 8 depends from claim 5/4/1. The Action is silent as to what element in Iwamoto constitutes the recited manual unlocking mechanism cylinder, and the projection rotatable in engagement with the cylinder. Nor does Iwamoto teach or suggest the recited features. It follows that the combined references would not have resulted in recited claim 8.

Claim 9

Claim 9 depends from claim 1. As previously discussed (Issue #2), Lavigne does not teach the recited sensor nor the refrigerator/sensor/computer relationship. The Action is silent as to where Iwamoto teaches or suggests the recited features and relationships. Nor does Iwamoto teach or suggest the recited features and relationships. The Office has not established a *prima facie* showing of obviousness.

Claim 10

Claim 10 depends from claim 9/1. Neither of the references, taken alone or in combination, teach or suggest a system for providing medical items having the recited relationships of a refrigerator lock module, a movable lever, a catch, a pawl, a solenoid, where the catch can engage the pawl and lever, where the pawl moves responsive to the door moving to an open position, and where a sensor can sense the position of the pawl. Where do the references teach or suggest, for example, an arrangement in which a sensor can sense opening of a

refrigerator door via the positioning of a pawl? The Office has not established a *prima facie* showing of obviousness. Thus, even if it were somehow possible for the references to be combined as alleged, the combination still would not have resulted in the claimed invention.

Claim 11

Claim 11 depends from claim 10/9/1. The Action apparently relies on Lavigne for the recited bolt features. The Action alleges that Lavigne has a bolt that goes through a door (at col. 3, lines 38-50). However, nowhere does Lavigne mention a "bolt". Furthermore, even if Lavigne taught a bolt going through a door as alleged, claim 11 recites a bolt that extends inside a lock module and operatively engages a pawl. That is, the Examiner has not addressed the actual claim language. The Office has not established a *prima facie* showing of obviousness.

Claim 21

Claim 21 depends from claim 1. The Action is silent as to where the references teach or suggest a lock that returns to a locked condition upon a closing of a medical item refrigerator door. The Office has not established a *prima facie* case of obviousness.

The Claims Are Not Obvious Over Lavigne in view of Genest

(Issue #21)

Claims 11-15 and 23 were rejected under 35 U.S.C. § 103(a) as obvious over Lavigne in view of Genest. The Action admits that Lavigne does not teach or suggest the features and relationships recited in claims 12-15 and 23.

Claim 11

Claim 11 depends from claim 10/9/1. The Action apparently relies on Lavigne for the recited bolt features. The Action alleges that Lavigne has a bolt that goes through a door (at col. 3, lines 38-50). However, nowhere does Lavigne mention a "bolt". Furthermore, even if Lavigne taught a bolt going through a door as alleged, claim 11 recites a bolt that extends inside a lock module and operatively engages a pawl. That is, the Examiner has not addressed the actual claim language. The Office has not established a *prima facie* showing of obviousness.

Claim 12

Claim 12 depends from claim 1. Genest is not directed to a system for providing medical items, where the system has a lock module operatively attached to a refrigerator. Genest is non-analogous art. Genest is directed to a lock (having a rotary latch wheel) for a hotel room door (col. 1, lines 11-22). The lock is actuable in response to both insertion of an appropriate data combination code from a first side of the lock and movement of a handle from a second side of the lock (col. 1, lines 65-68).

Genest's lock is not mounted in supporting connection with an external surface of a refrigerator. Where does Genest even mention a refrigerator? Nor does Genest's lock comprise a

bolt that is capable of being in supporting connection with an external surface of a refrigerator door. Rather, Genest's latch wheel (38) extends beyond the edge of the door to engage a keeper (46) secured to the door jamb (col. 4, lines 46-62). Genest does not teach or suggest the features for which it was relied upon, especially at col. 9, lines 22-30.

The Office has not established a *prima facie* showing of obviousness. It would not have been obvious to one having ordinary skill in the art to have combined the references as alleged to have produced the recited invention.

Claim 13

Claim 13 depends from claim 12/1. Neither of the references, taken alone or in combination, teach or suggest a bolt operatively attached to both the front surface and a side surface of a refrigerator door. A *prima facie* case of obviousness has not been established.

Claim 14

Claim 14 depends from claim 12/1. Neither of the references, taken alone or in combination, teach or suggest a bolt attached to a refrigerator door through a bolt supporting bracket that renders the bolt inaccessible from outside the lock module. Again, the Office has not established a *prima facie* showing of obviousness.

Claim 15

Claim 15 depends from claim 14/12/1. The references, taken alone or in combination, further do not teach or suggest a bolt supporting bracket having a cover that extends in overlying relation of fasteners. A *prima facie* case of obviousness has not been established.

Claim 23

Claim 23 depends from claim 1. The references, taken alone or in combination, further do no teach or suggest a lock module including a retrofit assembly which is attached by fasteners to an exterior surface of a refrigerator. The Action is silent as to where the relied upon Genest teaches or suggests the alleged lock module including a retrofit assembly. Again, the Office has not established a *prima facie* showing of obviousness.

Claim 41 Is Not Obvious Over Colson '450 in view of McDonald

(Issue #22)

Claim 41

Claim 41 depends from claim 27. The Action admits that Colson '450 does not teach or suggest the recited features and relationships. Appellants' previous remarks in Issue #3 further distinguish claim 41 from Colson '450.

McDonald does not teach or suggest opening a refrigerator door to access its interior area; sensing with a sensor that the door was opened; and responsive to the sensing, changing a refrigerator lock condition to cause the door to be held closed when the door is next closed. Where does McDonald even mention a refrigerator? McDonald cannot alleviate the admitted (and other previously noted) deficiencies in Colson '450. The Office has not established a *prima facie* case of obviousness.

Claim 41 Is Not Obvious Over Colson '450 in view of Weinberger

(Issue #23)

Claim 41

Claim 41 depends from claim 27. The Action admits that Colson '450 does not teach or suggest the recited features and relationships. Appellants' previous remarks in Issue #3 further distinguish claim 41 from Colson '450.

Weinberger does not teach or suggest opening a refrigerator door to access its interior area; sensing with a sensor that the door was opened; and responsive to the sensing, changing a refrigerator lock condition to cause the door to be held closed when the door is next closed. Where does the Weinberger even mention a refrigerator? Weinberger cannot alleviate the admitted (and other previously noted) deficiencies in Colson '450.

Weinberger at col. 13, lines 20-30 refers to an opening sensed by a switch to display a messages such as "confirm to continue" and "close cover to continue". The relied upon section of Weinberger is not directed to causing a door lock to change to the locked condition responsive to the door opening. Weinberger does not link sensing a *door* opening to placing a lock in a locked condition. The Office has not established a *prima facie* case of obviousness.

The Action apparently asserts that Weinberger includes locking a door responsive to a sensor indicating *closure* (of a *cover*). However, claim 41 enables changing a lock to a locked condition upon sensing an *opening* (of a *door*). Locking a *door* upon *opening* differs from the alleged modification of locking a *cover* upon *closing*. Further, the citation of Weinberger is an example of the fact that the Office considers a "drawer" and a "door" to be the same thing (and

also provides that Appellants are entitled to a reduction to practice of at least claims 24 and 45 prior to March 7, 1994). However, if the Board decides that a "door" differs from a "drawer", then Weinberger fails to teach this feature of the recited invention.

The Claims Are Not Obvious Over Colson '450 in view of Higham

(Issue #24)

Claims 30 and 41 were rejected under 35 U.S.C. § 103(a) as obvious over Colson '450 in view of Higham. The Action admits that Colson '450 does not teach or suggest the recited features and relationships.

Claim 30

Claim 30 depends from claim 28/27. Claim 30 recites that the lock module (attached to the exterior surface of the refrigerator body) further comprises a visual indicator that can indicate that the refrigerator interior is able to be accessed.

For reasons already discussed (in Issue #5, claim 46), Higham does not teach or suggest a refrigerator lock module having a visual indicator. Nor does Higham teach or suggest using a visual indicator to indicate that a refrigerator interior can be accessed. In Higham, at best the visual indicators are used to indicate which "drawer" or rack has the item, and they are then used to indicate the location of the item in that particular drawer or rack (col. 7, lines 1-6). Where does Higham discuss or mention a refrigerator? The Office has not established a *prima facie* case of obviousness.

Claim 41

Claim 41 depends from claim 27. The Action admits that Colson '450 does not teach or suggest the recited features and relationships. Appellants' previous remarks in Issue #3 further distinguish claim 41 from Colson '450.

Higham does not teach or suggest opening a refrigerator door to access its interior area; sensing with a sensor that the door was opened; and responsive to the sensing, changing a refrigerator lock condition to cause the door to be held closed when the door is next closed.

Where does the Higham even mention a refrigerator? Higham cannot alleviate the admitted (and other previously noted) deficiencies in Colson '450. The Office has not established a *prima facie* case of obviousness.

CONCLUSION

Each of Appellants' pending claims specifically recites features and relationships that are neither disclosed nor suggested in the applied prior art. Furthermore, the applied prior art is devoid of any teaching or suggestion for combining features thereof to produce the recited invention. Nor has the Office identified a valid reason for combining prior art features. Appellants' claims patentably distinguish over the applied references. For these reasons it is respectfully submitted that all the pending claims are allowable.

Respectfully submitted,



Ralph E. Jocke

Reg. No. 31,029

Daniel D. Wasil

Reg. No. 45,303

WALKER & JOCKE

231 South Broadway

Medina, Ohio 44256

(330) 721-0000

(viii)



CLAIMS APPENDIX

1. A system for providing medical items comprising:

a computer, wherein the computer is in operative connection with a data store, wherein the data store includes user data representative of a plurality of authorized users, item data representative of a plurality of medical items, and location data representative of storage locations in which the medical items are stored;

a user interface in operative connection with the computer, wherein the interface includes an input device;

a refrigerator, wherein a storage location for at least one medical item is located in an interior area of the refrigerator, the refrigerator including a door, wherein access to the interior area is controlled by opening and closing the door;

a lock module operatively attached to the refrigerator, wherein the lock module is in operative connection with the computer, and wherein the lock module is operative responsive to a signal from the computer to change the lock module from a locked to an unlocked condition, wherein in the locked condition the refrigerator is prevented from being opened and in the unlocked condition the door is enabled to be opened;

wherein responsive to a user inputting identification data through the input device of the interface corresponding to the data representative of an authorized user stored in the data store, the computer enables the user to input item indicia corresponding to a medical item through the input device, and wherein the computer is operative responsive to input of the item indicia to output the signal changing the lock module to the unlocked condition.

2. The system according to claim 1 and wherein the lock module further comprises a visual indicator, and wherein the visual indicator provides an indication responsive to the signal that the door is enabled to be opened.
3. The system according to claim 1 and wherein the lock module further comprises a door sensor, wherein the door sensor is operative to generate an open signal responsive to opening the door, and wherein the computer is operative responsive to the open signal to change the lock module to the locked condition, wherein when the door is next returned to a closed condition the door is held therein.
4. The system according to claim 1 wherein the lock module further comprises a manual unlocking mechanism, and wherein the lock module is enabled to be changed to the unlocked condition responsive to the manual unlocking mechanism.
5. The system according to claim 4 wherein the lock module includes a movable lever, and

further comprising a catch, and wherein the lock module includes a pawl, wherein the catch is engageable to hold the pawl in a first lever position and to release the pawl in a second lever position, and wherein the pawl is operatively engageable with the door of the refrigerator, and further comprising a solenoid in operative connection with the lever, and wherein the manual unlocking mechanism is engageable with the lever, and wherein the lock module is changed to the unlocked condition by either the unlocking mechanism or the solenoid moving the lever from the first position to the second position.

6. The system according to claim 5 wherein the lever is rotatably movable about a pivot, and wherein the solenoid is engageable with the lever on a first side of the pivot and the manual unlocking mechanism is engageable with the lever on a second side of the pivot.
7. The system according to claim 5 wherein the catch comprises a tapered step on the lever.
8. The system according to claim 5 wherein the manual unlocking mechanism includes a cylinder, and a projection rotatable in engagement with the cylinder, and wherein the projection is engageable with the lever to move the lever to the second position.
9. The system according to claim 1 and further comprising a sensor, wherein the sensor is operative to sense opening of the refrigerator door, and wherein the sensor is operative to generate an open signal responsive to opening the refrigerator door, and wherein the computer is operative responsive to the open signal to store data representative of an event of opening the refrigerator door in the data store.

10. The system according to claim 9 wherein the lock module includes a movable lever, and further comprising a catch, and wherein the lock module further includes a movable pawl, and wherein the lock module is held in the locked position when the catch engages the pawl, and wherein the lock module further includes a solenoid, and wherein the solenoid is operative responsive to the signal to move the lever to disengage the catch, and wherein the pawl moves responsive to the door moving to the open position, and wherein the sensor is operative to sense the position of the pawl.
11. The system according to claim 10 and further comprising a bolt in operative connection with the door, and wherein in the closed position of the door the bolt extends inside the lock module and operatively engages the pawl.
12. The system according to claim 1 wherein the lock module is mounted in supporting connection with an external surface of the refrigerator, and further comprising a bolt in supporting connection with an external surface of the refrigerator door, and wherein in a closed position of the door the bolt extends inside the lock module.
13. The system according to claim 12 wherein the refrigerator door includes a front surface and a side surface, and wherein the bolt is operatively attached to both the front surface and the side surface of the door.
14. The system according to claim 12 wherein the bolt is attached to the door through a bolt

supporting bracket, and wherein in the closed position of the door the bolt supporting bracket is adjacent the lock module so as to render the bolt inaccessible from outside the lock module.

15. The system according to claim 14 wherein the bolt supporting bracket is operatively connected to the refrigerator door through fasteners, and wherein the bolt supporting bracket further includes a cover, wherein the cover extends in overlying relation of the fasteners.
16. The system according to claim 1 wherein the input device includes a reading device, and wherein the item indicia is input through the reading device.
17. The system according to claim 16 wherein the refrigerator includes machine readable indicia thereon, and wherein the item indicia is input by reading the machine readable indicia with the reading device.
18. The system according to claim 16 and further comprising a report having machine readable indicia thereon, and wherein the item indicia is input by reading the machine readable indicia on the report.
19. The system according to claim 18 and further comprising a printer in operative connection with the computer, wherein the computer is operative to cause the printer to print the report.

20. The system according to claim 16 wherein the interior area of the refrigerator includes at least one machine readable indicia therein, whereby after opening the refrigerator door and taking the medical items stored therein a user is enabled to read the machine readable indicia, wherein the computer is operative responsive to the reading of the machine readable indicia to include data in the data store representative of the taking of the medical item from the interior area of the refrigerator.
21. The system according to claim 1 wherein when the lock module is in the unlocked condition and the door is opened, the lock module returns to the locked condition upon the subsequent closing of the door.
22. The system according to claim 9 wherein when the lock module is changed to the unlocked condition and the door is not opened for a time out period, the lock module returns to the locked condition, and wherein the computer is operative responsive to the lock module returning to the locked condition without the door having been opened to store data representative of the door not being opened in the data store.
23. The system according to claim 1 wherein the lock module includes a retrofit assembly which is attached by fasteners to an exterior surface of the refrigerator.
24. A system for providing medical items comprising:

a computer, wherein the computer is in operative connection with a data store, wherein the data store includes user data representative of a plurality of authorized users, item data representative of a plurality of medical items, and location data representative of storage locations in which the medical items are stored;

a user interface in operative connection with the computer, wherein the interface includes an input device;

a preexisting housing structure, wherein a storage location for at least one medical item is located in an interior area of the housing structure, the housing structure including a door, wherein access to the interior area is controlled by opening and closing the door;

a lock module mounted on an exterior surface of the housing structure, wherein the lock module is in operative connection with the computer, and wherein the lock module is operative responsive to a signal from the computer to change the lock module from a locked to an unlocked condition, wherein in the locked condition the door is prevented from being opened and in the unlocked condition the door is enabled to be opened;

wherein responsive to a user inputting identification data through the input device of the interface corresponding to the data representative of an authorized user stored in the data store, the computer enables the user to input item indicia

corresponding to a medical item through the input device, and wherein the computer is operative responsive to input of the item indicia to output the signal changing the lock module to the unlocked condition.

25. The system according to claim 24 wherein the lock module further includes a door sensor in operative connection with the door and the computer, and a latching device wherein the latching device is operative to selectively maintain the lock module in the locked and unlocked conditions, wherein the latching device is operative to hold the lock module in the unlocked position responsive to the signal, and thereafter the computer is operative to cause the output of a further signal, wherein the further signal changes the lock module to a locked condition and thereafter the latching device holds the lock module in the locked condition, and wherein the computer is operative to cause the further signal to be output responsive to the earlier of at least one of the door sensor sensing opening of the door and the passage of a time delay period after output of the signal without the door sensor sensing opening of the door.

26. The system according to claim 25 wherein the latching device includes a permanent magnet latching solenoid.

27. A method comprising the steps of:

attaching a lock module to a refrigerator, wherein the lock module selectively enables accessing an interior area of the refrigerator;

placing a medical item in the interior area of the refrigerator;

storing in a data store data representative of a type associated with the medical item placed in the interior area;

inputting through an input device an input corresponding to the type of medical item stored in the interior area;

determining with a computer in operative connection with the data store, the lock module and the input device, that the type of medical item corresponding to the input is stored in the interior area;

generating a signal with the computer responsive to the determination that the medical item is stored in the interior area;

enabling access to the interior area with the lock module responsive to the signal generated by the computer.

28. The method according to claim 27 wherein the refrigerator comprises a body and a door, and wherein the attaching step comprises attaching the lock module to an exterior surface of the body, and a bolt supporting bracket to a further exterior surface of the door, wherein the bolt supporting bracket is in operative connection with a bolt, and wherein in

the enabling step the lock module releases the bolt.

29. The method according to claim 28 wherein the attaching step further includes attaching the bolt supporting bracket to the further exterior surface of the door with at least one fastener, and then covering the fastener by installing a cover.
30. The method according to claim 28 wherein the lock module further comprises a visual indicator, and further comprising the step of indicating with the visual indicator that the interior of the refrigerator is enabled to be accessed.
31. The method according to claim 27 wherein the placing step further includes placing medical items in a plurality of storage locations, at least one of the locations being in the interior area and at least one of the locations being outside the interior area, and wherein the storing step includes storing data representative of the types of medical items placed respectively in the interior area and outside the interior area.
32. The method according to claim 31 wherein in the placing step a first type of medical item is placed in the storage location in the interior area and a second type of medical item is placed in the other storage location, and prior to the inputting step further comprising the step of displaying on a display device indicia representative of both the first type of medical item and the second type of medical item.
33. The method according to claim 31 wherein the other location in which the second type of

medical item is stored is in a dispenser, wherein the dispenser is in operative connection with the computer and the input device, and further comprising the steps of:

inputting through the input device a second input corresponding to the second type of medical item stored in the dispenser;

determining with the computer that the second type of medical item is stored in the dispenser;

generating a second signal with the computer responsive to the determination that the second type of medical item is stored in the dispenser;

dispensing the second type of medical item from the second location in the dispenser responsive to the second signal.

34. The method according to claim 27 and prior to the inputting step further comprising the step of labeling the refrigerator with a machine readable indicia corresponding to the interior area, and wherein the inputting step includes reading the machine readable indicia with a reading device.
35. The method according to claim 34 wherein the machine readable indicia includes a bar code and the reading device includes a bar code scanner.

36. The method according to claim 27 wherein the refrigerator includes a refrigerator door, and further comprising the steps of:

opening the refrigerator door, whereby the interior area is accessible;

sensing with a sensor, in operative connection with the computer that the refrigerator door has been opened;

storing in the data store data representative of the opening of the door.

37. The method according to claim 36 wherein the storing step includes storing in the data store data representative of a plurality of authorized users, wherein the authorized users are authorized to access medical items in the interior area of the refrigerator, and prior to the enabling step further comprising the steps of:

providing through an input device data representative of an authorized user;

comparing with the computer whether the data provided in the providing step corresponds to one of the authorized users, wherein in the absence of such correspondence the generating step, enabling step and opening step are not performed.

38. The method according to claim 37 wherein when in the comparing step the data

corresponds to one authorized user, and the opening step is performed, the further storing step includes storing data representative of the one authorized user in correlated relation with the data representative of opening the door.

39. The method according to claim 27 and wherein the lock module further includes a manual unlocking mechanism, and after the enabling step further comprising the steps of:

preventing access to the interior area with the lock module;

manually actuating the unlocking mechanism on the lock module; and

accessing the interior area.

40. The method according to claim 39 wherein the lock module includes a lever movable about a pivot, wherein movement of the lever in a first rotational direction enables accessing the interior area, and wherein in the enabling step a first mechanism engages the lever on a first side of the pivot and moves the lever in the first direction, and wherein in the manually actuating step a second mechanism engages the lever on an opposed side of the pivot and moves the lever in the first direction.

41. The method according to claim 27 and further comprising the steps of:

accessing the interior area by opening a door;

sensing with a sensor that the door is open, wherein the sensor is in operative condition with the computer;

changing a condition of the lock module responsive to the sensor sensing that the door has been opened, wherein the door is held in a closed position by the lock module when the door is next closed.

42. The method according to claim 27 wherein access to the interior area is controlled by a door, and wherein the storing step includes storing in the data store data representative of a plurality of authorized users, wherein the authorized users are authorized to access medical items in the interior area of the refrigerator, and prior to the enabling step further comprising the steps of:

providing through an input device data representative of an authorized user;

comparing with the computer whether the data provided in the providing step corresponds to one of the authorized users, the enabling step being performed responsive to the data corresponding to one of the authorized users;

sensing with a sensor in operative connection with the computer that the door has not been opened;

generating a further signal with the computer a time period after the door is

enabled to be opened responsive to the sensor not sensing opening of the door,
wherein the further signal is operative to cause the lock module to hold the door in
a closed position.

43. The method according to claim 42 and further comprising the step of storing in the data store data representative of the door being enabled to open by the one authorized user, and not being opened.

44. A method comprising the steps of:

attaching a lock module to a preexisting housing structure, wherein the lock module selectively enables accessing an interior area of the housing structure;

placing a medical item in the interior area of the housing structure;

storing in a data store data representative of a type associated with the medical item placed in the interior area;

inputting through an input device an input corresponding to the type of medical item stored in the interior area;

determining with a computer in operative connection with the data store, the lock module and the input device, that the type of medical item corresponding to the

input is stored in the interior area;

generating a signal with the computer responsive to the determination that the medical item is stored in the interior area;

enabling access to the interior area with the lock module responsive to the signal generated by the computer.

45. A system for providing medical items comprising:

a computer, wherein the computer is in operative connection with a data store, wherein the data store includes user data representative of a plurality of authorized users, item data representative of a plurality of medical items, and location data representative of storage locations in which the medical items are stored;

a user interface in operative connection with the computer, wherein the interface includes at least one input device;

a housing, wherein a storage location for at least one medical item is located in an interior area of the housing, the housing including a door, wherein access to the storage location is controlled by opening and closing the door;

a lock in operative connection with the housing, wherein the lock is in operative

connection with the computer, and wherein the lock is operative responsive to at least one signal from the computer to change the lock from a locked to an unlocked condition, wherein in the locked condition the door is prevented from being opened and in the unlocked condition the door is enabled to be opened;

wherein responsive to a user inputting through the at least one input device identification data corresponding to data for an authorized user stored in the data store, the computer enables the user to input item indicia corresponding to a medical item through the at least one input device, and wherein the computer is operative responsive to input of the item indicia to output the at least one signal changing the lock to the unlocked condition.

46. The system according to claim 45 and wherein the lock further comprises a visual indicator, and wherein the visual indicator provides an indication responsive to the at least one signal that the door is enabled to be opened.
47. The system according to claim 45 and wherein the lock further comprises a door sensor, wherein the door sensor is operative to generate an open signal responsive to opening the door, and wherein the computer is operative responsive to the open signal to change the lock to the locked condition, wherein when the door is next returned to a closed condition the door is held therein.

48. A system for providing medical items comprising:

a user interface,

wherein the interface includes at least one user input device,

at least one data store,

wherein the at least one data store stores item data representative of each of a plurality of medical items,

wherein the at least one data store stores location data corresponding to each of a plurality of storage locations in which the plurality of medical items are stored,

wherein the at least one data store stores data corresponding to a plurality of user identifiers, wherein each user identifier is representative of a different authorized user,

at least one computer,

wherein the at least one computer is in operative connection with the data store,

wherein the at least one computer is in operative connection with the user interface,

wherein the at least one computer is operative to determine whether data received with the at least one user input device corresponds in the data store to an authorized user,

wherein the at least one computer is operative to determine whether data received with the at least one user input device corresponds in the data store to a particular one of the plurality of medical items,

a medical item housing,

wherein the housing includes a medical item storage location for at least one medical item represented by item data in the data store,

wherein the medical item storage location is represented by location data in the data store,

a lock,

wherein the lock selectively controls access to the medical item storage

location,

wherein the lock in a locked condition prevents access to the
medical item storage location,

wherein the lock in an unlocked condition permits access to the
medical item storage location,

wherein the lock is in operative connection with the at least one computer,

wherein the lock is operative responsive to at least one signal from
the at least one computer to change from the locked condition to
the unlocked condition,

wherein responsive to the at least one user input device receiving input that
corresponds to a particular user identifier in the data store, the at least one
computer allows input to be received through the at least one user input device
that corresponds to a particular one of the plurality of medical items represented in
the data store,

wherein responsive to the at least one user input device receiving input
that corresponds to a particular one of the plurality of medical items, the at
least one computer causes output of the at least one signal.

49. The system according to claim 48 wherein the housing includes a door associated with the lock, wherein in the locked condition the door is prevented from being opened, wherein in the unlocked condition the door is enabled to be opened, and wherein when the door is open a medical item in the medical item storage location can be manually removed therefrom.
50. The system according to claim 48 wherein the housing includes a drawer associated with the lock, wherein in the locked condition the drawer is prevented from being opened, wherein in the unlocked condition the drawer is enabled to be opened, and wherein when the drawer is open a medical item in the medical item storage location can be manually removed therefrom.

(ix)

EVIDENCE APPENDIX

The record shows that the Board of Patent Appeals and Interferences already has a copy of the 37 C.F.R. § 1.131 Declaration filed September 27, 2000. For example, the Remand dated June 12, 2006 (at pages 4-5) refers to the Declaration. Thus, the Notice from the Examiner dated May 29, 2008 is unreasonable and should be vacated. Reconsideration is respectfully requested.

Nevertheless, to appease the Examiner, attached is another (unnecessary) copy of the Declaration filed September 27, 2000. This copy was obtained using the Patent Office's PAIR system. Thus, the attached copy is a merely a copy of an imaged copy that the Office (including the Examiner and the Board) already possesses. Thus, the Notice is further unreasonable.

The prosecution history shows that the Examiner in the Office Action dated November 7, 2000 entered the Declaration into the record. The prosecution history also shows that the Board's Remand to the Examiner acknowledges that the record contains the Declaration.



#12
10-2602

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | | |
|------------------------------|---|-------------------|
| In re Application of |) | |
| David T. Frederick, et al. |) | Art Unit: 3651 |
| |) | |
| Serial No.: 09/086,857 |) | Patent Examiner |
| |) | Michael E. Butler |
| Filed: May 29, 1998 |) | |
| |) | |
| For: System For Tracking And |) | |
| Dispensing Medical Items |) | |
| From Environmentally |) | |
| Controlled Storage Area |) | |

Commissioner of Patents and Trademarks
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. Section 1.131

R. Michael McGrady hereby declares as follows:

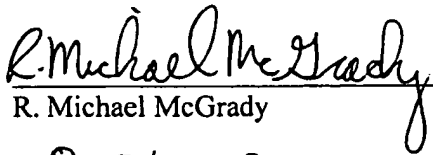
1. I am an Applicant of the Patent Application identified above and am the sole inventor of the subject matter described and claimed in claims 24 and 45 thereof.
2. I have personal knowledge of all matters set forth in this Declaration.
3. At all times mentioned herein I have been an employee of Diebold, Incorporated, the Assignee of the invention claimed in the Patent Application identified above, or its predecessor entity, MedSelect Systems, Inc. which has now merged into Diebold, Incorporated.
4. Prior to March 7, 1994 I had completed my invention as described and claimed in the subject application in claims 24 and 45, in this country as evidenced by the following:
 - a. Prior to March 7, 1994 having conceived of the idea of a system and method for providing medical items, I produced the Functional Specification (Software) document, the pertinent portions of which are attached hereto as Exhibit A.

- b. Prior to March 7, 1994 at the facilities of MedSelect Systems, Inc. located in Cranberry Township, Pennsylvania (now Diebold, Incorporated, the assignee of the subject Application) I assembled a system for dispensing medical items as described in Exhibit A and successfully tested its operation. The system included a computer with an associated data store which held data corresponding to a plurality of authorized users, a plurality of medical items and a plurality of storage locations in which medical items were stored. The system further included a user interface which included a display terminal with input devices including a card reader and "buttons" on a touch screen. The system further included a housing structure with an interior area having access thereto controlled by a door, and with a storage location for holding a plurality of medical items within the housing structure. The system further included a lock assembly on the housing structure, the lock being operatively connected to the computer such that the computer controlled the lock to change the lock between the locked and unlocked conditions, the door being prevented from opening when the lock was in the locked condition. The computer in the system was programmed and the system operated successfully such that when a user input identification data through the input devices which corresponded to data for an authorized user stored in the data store, the computer operated to allow the user to input data corresponding to a medical item through an input device. The computer then operated to generate signals which changed the lock from the locked to the unlocked condition. This enabled the user to open the door of the housing structure to access the medical items in the interior area of the housing. The makeup of the system and the method of operation thereof being described in Exhibit A hereto.

5. As can be seen from Exhibit A, the invention as claimed in each of claims 24 and 45 was completed by being conceived and reduced to practice in this country prior to March 7, 1994. Each of the dates deleted from Exhibit A is prior to March 7, 1994.

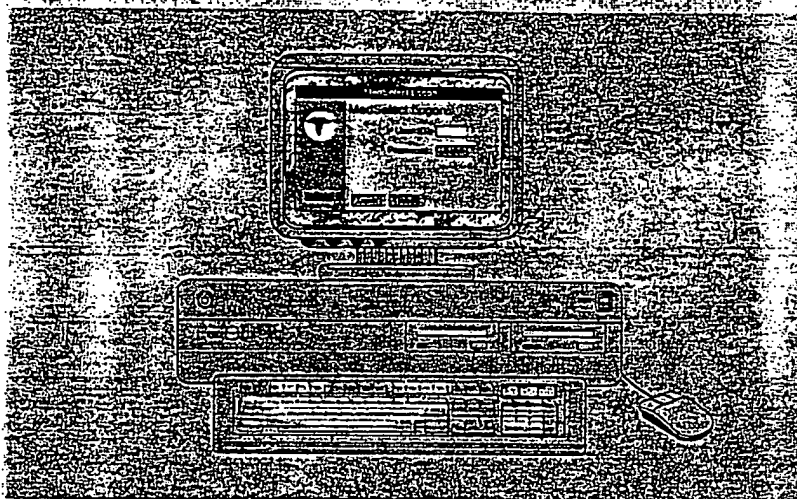
6. The invention which is described and claimed in the above-identified Application, was not in public use or on sale more than one year before December 16, 1994, the filing date of Patent Application Serial No. 08/367,783 from which the above-identified Application claims priority pursuant to 35 U.S.C. Section 120.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information are believed to be true, and further that such statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both (18 U.S.C. Section 1001) and may jeopardize the validity of the application or any patent issuing thereon.


R. Michael McGrady
8-31-00
Date

Selectrac

Functional Specification (Software)



MedSelect
MEDICAL EQUIPMENT SUPPLY COMPANY

System Functional Specification

1.1 Introduction

The System Functional Specification defines as completely as possible the specific tasks that the SelecTrac-CL and SelecTrac-Rx systems perform. It is the blueprint that is used to program the systems and to verify that the systems satisfy the criteria used to define them.

SelecTrac-CL and SelecTrac-Rx are both designed to store, count, and dispense supplies (such as catheters, guides, sheaths, etc.) and medications (such as syringes, vials, ampoules, packaged solids, etc.).

Chapter 1.2 explains the general functions of the SelecTrac systems.

1.2 System Function Overview

The SelecTrac Systems can be used separately or in conjunction with each other. This is accomplished in the logical database design which allows the products to share a common physical database structure.

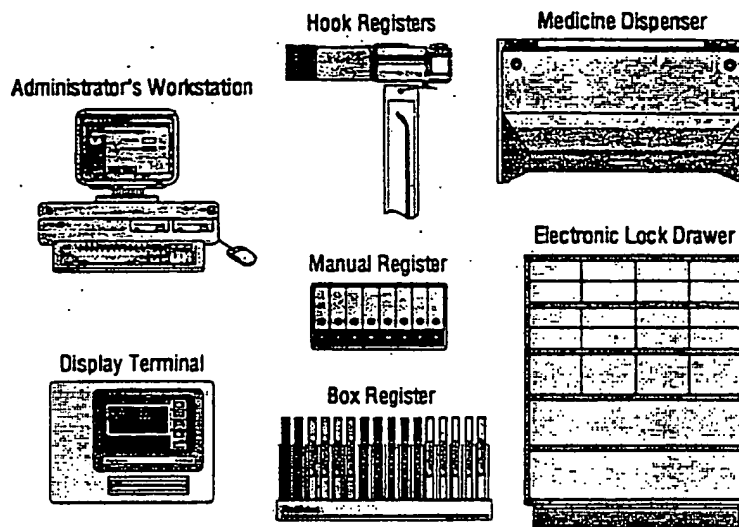


Figure 1.2-1. The SelecTrac System

The SelecTrac-CL system monitors the storage and utilization of supplies for Cardiac Labs. It tracks this inventory by using intelligent hooks, box registers, manual registers and manual data entry.

The SelecTrac-Rx system monitors the storage and utilization of medicines and controls the dispensing of these medicines for Nursing Stations and other hospital areas. It uses medicine dispensers (vials and solids), electronic lock cabinets (ELCs), and manual data entry to provide this functionality. A network link to the Hospital Information System (HIS) delivers orders from the pharmacy to the nursing station.

Both systems provide data forms for user data entry and reporting. They also have internal diagnostic capability. See Appendix 1 for a definition of each component of the SelecTrac Systems.

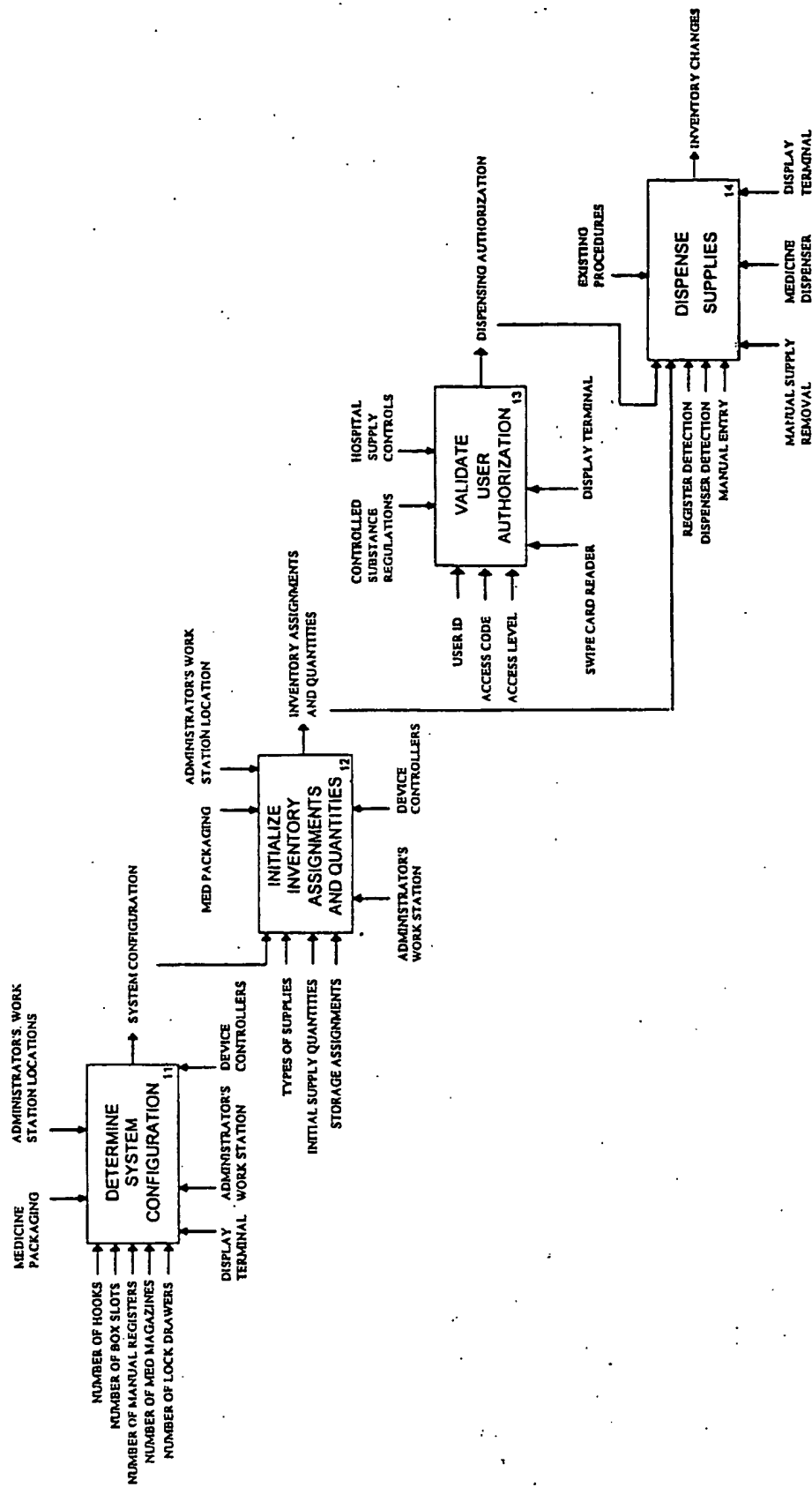


Figure 1.3-3. Monitor Working Inventory

Node A1

Node A1: Monitor Working Inventory

Figure 1.3-3 shows how the SelecTrac Systems monitor the working inventory.

Process 11: Determine System Configuration

The number and physical location of hook registers, box registers, manual registers for SelecTrac-CL systems and medicine dispenser magazines, and electronic lock cabinets (ELCs) for SelecTrac-Rx systems must be manually entered at the Administrator's Workstation (AWS) when the system is installed.

Non-system storage may also be manually configured and maintained within the SelecTrac system. An artificial controller address and position will be created by the system.

Process 12: Initial Inventory Quantities/Assignments

A list of all supplies to be controlled may be selected from a master supply list or manually entered at the AWS.

When more than one storage position is assigned the same supply, these positions may be treated as a position group for minimum quantity calculations.

The type of supply and initial quantity assigned to each register, medicine dispenser magazine, and electronic lock cabinet must be entered manually at the AWS.

Process 13: Validate User Authorization

Some supplies may require controlled access because of Government Regulations (as in the handling of narcotics) or the hospital's desire to control expensive supplies. These supplies must be kept in an ELC or medicine dispenser. Access to these supplies will be granted only after a valid user ID and personal identification number (PIN) are provided to the system at a display terminal. A swipe card for automatic entry of an identified user will be provided but the PIN must be entered manually. Any supply or medicine can require a second user ID and PIN. The user should logout when done dispensing, but the system will automatically logout the user if there is no activity for 1 minute, as a security precaution.

For SelecTrac-CL, a user will logon by using a swipecard or a touch screen keypad, but a PIN will not be required. This will record the user's name with activities as long as the user has not logged out. There will not be an automatic logout.

Process 14: Dispense Supplies

Supplies are dispensed manually at the hook and box registers, but the system automatically senses the change in inventory. Note that the system also automatically detects returns and restocking.

Supplies are also dispensed at the manual register, but the person adding or removing the supply must indicate the change in inventory by pushing a button once for each supply.

Supplies dispensed by a Medicine Dispenser are automatically updated by the SelecTrac systems. In the event that the SelecTrac system believes a medicine was dispensed, but the medicine was not actually dispensed, the user must manually inform the system at a display terminal. The system will then inquire if the user wants the medication dispensed from another magazine, if possible. It will also indicate which magazine failed in the error log.

The SelecTrac system will unlock an ELC drawer with proper authorization, but the user must indicate the quantity of supplies taken, returned, or stocked at the display terminal.

DATA INTEGRITY

The SelecTrac Systems minimize the requirements for data entry. Instead of requiring many fields, the SelecTrac systems allow the customer to leave them empty. However, some functionality may not be available when the data doesn't exist. For example, Minimum, Maximum, and Par Quantities are not required, but a Below Par report has no usefulness without this data. Since this may be acceptable to customers, the SelecTrac Systems do not make these fields mandatory.

To prevent data loss in the event of a hard disk failure and to keep enough free disk space for the Selectrac Systems to run efficiently, data is periodically archived to tape. The archive will be run on the first day of each month.

The customer can choose an archive period specified in months. For all patient charts that have been closed for the the archive period prior to the first day of the month, the charts and their associated procedures, medication orders, and inventory events will be saved to magnetic tape and deleted from the hard disk.

1.6 Graphical User Interfaces

There are two types of user interface stations in the SelecTrac Systems:

1. Administrator's Workstation with Keyboard and Mouse
2. Display Terminal with Touch Screen

The Administrator's Workstation (AWS). This workstation is a PC running Paradox for Windows. The AWS is where Patient Information is entered and reports are created. The AWS is also where supplies are assigned to storage locations and user profiles are created and maintained. A SelecTrac system may have more than one Administrator's Workstation.

The Display Terminal. The Display Terminal provides a "Touch Screen" graphical user interface. Display Terminals will be placed strategically to provide information at the time and place where it is needed most. This interface design supports both the SelecTrac-CL and SelecTrac-Rx products and attempts to make the "look and feel" as similar as possible.

Table 1.6-1 shows the forms on the SelecTrac-CL and SelecTrac-Rx systems.

| SelecTrac-CL | SelecTrac-Rx |
|-----------------|--------------------|
| Logon | Logon |
| Patient Browser | Patient Browser |
| Patient Info | Patient Profile |
| Physician Card | Medication Order |
| Patient Usage | Patient Usage |
| | Supply Browser |
| | Supply Information |

The Patient Profile form is a single page form that displays the following:

| | |
|-------------------------------|----------------------------|
| Patient Name: Doe, John A | Patient ID Number: 9261346 |
| Gender: Male | Med Record Number: 001346 |
| Age: 52 | Date Admitted: 2/3/94 |
| Height: 190.23 cm | Time Admitted: 13:00 |
| Weight: 50.1 kg | Room #: 476 |
| Birthdate: 01/05/40 | Bed #: 2 |
| Allergies: penicillin | |
| Referral Physician: Dr. Smith | |

Figure 1.6-6. SelecTrac-CL Patient Profile

There is 1 graphical button on the SelecTrac-Rx Patient Profile form, starting in column 60. Touching this button has the following effect:

1. FINISH Returns to the Patient Browser form.

The Physician Card form displays supplies that are generally used by a physician for a particular type of procedure. The Physician Card form is a multiple page form to allow for any number of supplies to simultaneously be displayed.

| | | |
|----------------|-------------|---|
| Physician Name | | Music Preference |
| Procedure Name | | |
| Item | Supply Name | Manufacturer |
| | | <input type="button" value="Up"/> <input type="button" value="Down"/> |
| | | <input type="button" value="Finish"/> |

Figure 1.6-7. SelecTrac-CL Physician Card

Ten supplies can be displayed on a single page with each supply on one line of the form with the following information and positions:

| | |
|--------------|--|
| Column 1- 4 | Item Number (A sequential number assigned for reference) |
| Column 6- 13 | Status |
| Column 15-52 | Supply / Manufacturer |
| Column 54-59 | Number |
| Column 60-80 | Buttons |

SELECTRAC-Rx TOUCH SCREEN:

The first form encountered by a user is the Logon form (Figure 1.6-3). The Logon form has a keypad graphic that may be used to enter a User ID Number. This number could also be automatically read into the system by a magnetic card reader or bar code reader that are options supported by SelecTrac. The current magnetic card reader only reads track 2 which can only be the numbers 0 through 9, the question mark (?) as a string start character, the equals sign (=) as a field separator and the semicolon (;) as the end of string character. When the Logon form is displayed for more than 30 seconds, a screen saver program is activated. Touching the screen will bring up the Logon form again.

After the User ID Number has been entered, the user is prompted to enter a Personal Identification Number (PIN) using the graphical keypad. After the PIN has been entered, the Logon form validates the User ID Number and PIN combination against the user's profile on the Database Server. If the combination is invalid, a message indicating that the Logon has failed appears, and the Logon form is again presented to allow the next Logon attempt. If the combination is valid, the Patient Browser form is activated. The SelecTrac-Rx Logon times out after the hospital specified timeout period (for instance, 1 minute) of inactivity as a security measure.

| Room | Bed | Sex | Patient Name | Patient ID |
|------|-----|-----|---------------------|------------|
| 1011 | 1 | M | Johnson, Peter | 14-2001 |
| 1011 | 2 | M | Carr, Robert | 14-2040 |
| 1012 | 1 | F | Murray, Lisa | 14-2100 |
| 1012 | 2 | F | Coventry, Sarah | 14-2130 |
| 1018 | 2 | M | Pedellies, Lawrence | 14-2132 |
| 1018 | 3 | M | Schaler, James | 14-2400 |
| 1017 | 1 | F | Scott, Anna | 14-2435 |
| 1017 | 3 | F | Walker, Michael | 14-2455 |

Figure 1.6-8. *SelecTrac-Rx Patient Browser*

While the Patient Browser forms are similar for the SelecTrac-CL and SelecTrac-Rx systems, they are not identical.

The SelecTrac-Rx Patient Browser form (see Figure 1.6-8) displays patients assigned to each nursing station. The Patient Browser is a multiple page form to allow for any number of patients to simultaneously be in the system. Ten patients can be displayed on a single page with each patient on one line of the form with the following information and positions:

| | |
|--------------|-------------|
| Column 1- 4 | Room Number |
| Column 6- 8 | Bed Number |
| Column 10-15 | Sex |

| | |
|--------------|--------------|
| Column 17-46 | Patient Name |
| Column 48-59 | Patient ID |
| Column 60-80 | Buttons |

The SelecTrac-Rx Patient Browser form displays these patients sorted 1st by room, then by bed. Touching anywhere on the line that displays a patient's name and ID number indicates that this is the patient the user is referring to. Button actions will apply to this patient.

There are 7 graphical buttons on the SelecTrac-Rx Patient Browser form, starting in column 60. Touching each button has the following effect:

- | | |
|-----------------|---|
| 1. SELECT | Supplies are automatically assigned to the selected patient and the Supply Browser form is activated. |
| 2. PATIENT INFO | Displays the profile for this patient |
| 3. UP ARROW | Returns to the previous page of patients |
| 4. DOWN ARROW | Advances to the next page of patients |
| 5. HELP | Provides online instructions about using the current form |
| 6. USAGE | Displays the supplies that have been charged to a patient |
| 7. LOGOUT | Logs out and Returns to the Logon screen |

The Patient Profile form displays the following patient information:

| | |
|-------------------------------|---------------------------------------|
| Patient Name: Doe, John A | Patient ID Number: 9283348 |
| Gender: Male | Med Record Number: 003548 |
| Age: 52 | Date Admitted: 2/3/94 |
| Height: 190.23 cm | Time Admitted: 11:00 |
| Weight: 50.1 kg | Room #: 478 |
| Birthdate: 01/03/40 | Bed #: 2 |
| Allergies: penicillin | |
| Referral Physician: Dr. Smith | |
| | <input type="button" value="Orders"/> |
| | <input type="button" value="Finish"/> |

Figure 1.6-9. *SelecTrac-Rx Patient Profile*

There are 2 graphical buttons on the SelecTrac-Rx Patient Profile form, starting in column 60. Touching each button has the following effect:

- | | |
|-----------|--------------------------------------|
| 1. ORDERS | Activates the Medication Orders form |
| 2. FINISH | Returns to the Patient Browser form. |

The Medication Order form is activated by the ORDERS button on the Patient Profile Form. The Medications Order form is a multiple page form to allow for any number of med orders to simultaneously be displayed for a patient. Five med orders sorted with the PRNs listed last can be displayed on a single page. Each supply on one line of the form will display the following information and positions:

| | |
|---------------------|--|
| Line 1 Column 1-20 | Trade Name |
| Line 2 Column 1-20 | Generic Name |
| Line 1 Column 22-26 | Order Number (Assigned by pharmacy system) |
| Line 2 Column 22-26 | Order Quantity |
| Line 1 Column 28-36 | Dose/Units |
| Line 2 Column 28-36 | Unit Dose/Units |
| Line 1 Column 38-44 | Route |
| Line 2 Column 38-44 | Freq |
| Line 1 Column 46-59 | Start Date/Time |
| Line 2 Column 46-59 | End Date/Time |

| Patient Name: Doe, John A. | | Patient ID: 123345 | | | | Dispense |
|----------------------------|-----------|--------------------|-------|--------|-------|------------|
| Trade Name | Order Qty | Dose Unit Dose | Route | Start | End | |
| Generic Name | | | | | | |
| Zestril | 7322 | 350mg | oral | 6/6/94 | 14:00 | Med Info |
| Lisinopril | 1 | 350mg | QID | 6/6/94 | 11:00 | |
| Glaxatin | 7325 | 100mg | oral | 6/6/94 | 13:00 | Up Arrow |
| Phenytoin | 2 | 50mg | BID | 6/7/94 | 12:00 | Down Arrow |
| Carvedilol | 7330 | 65/650 | oral | 6/8/94 | 15:00 | Help |
| Wygeiso | 1 | 65mg | PRN | 6/8/94 | 18:00 | Finish |

Figure 1.6-10. *SelecTrac-Rx Medication Order Form*

The Medication Order form has three graphical buttons, starting in column 60. Touching each button has the following effect:

1. DISPENSE A unit dose of the selected supply is dispensed or an Electronic Lock Cabinet drawer is opened. If the supply is in an electronic lock cabinet, the user is prompted to enter the quantity taken on a graphical keypad. If this supply requires a witness before dispensing (2nd PIN required flag), the Logon form will be displayed so that a 2nd user may logon as a witness. After the witness is verified, dispensing proceeds. If the hospital wants the remaining count verified (ELC count required flag), then the user will be prompted to enter the count remaining in the opened drawer. In either case, the supplies are automatically assigned to the selected patient.
2. MED INFO Displays the Medication Order for this supply (see Figure 1.6-11)
3. UP ARROW Returns to the previous page of medication orders
4. DOWN ARROW Advances to the next page of medication orders
5. HELP Provides online instructions about using the current form
6. FINISH Returns to the Patient Browser form.

The Supply Browser form is a multiple page form to allow for any number of supplies and medicines to simultaneously be in the system. The Supply Browser is not accessible at hospitals that choose the "med order only" option in the hospital configuration table.

| Brand Name | Generic Name | Strength | Form |
|------------|--------------|----------|---------|
| Demoral | meperidine | 50mg | tablet |
| Demoral | meperidine | 75mg | tablet |
| Sublimaze | fentanyl | 2 mg x 1 | ampoule |
| Sublimaze | fentanyl | 5ml | ampoule |
| Sublimaze | fentanyl | 10 ml | ampoule |
| Versed | midazolam | 2mg/2ml | vial |
| Versed | midazolam | 10mg/2ml | vial |
| | duramorph | 5mg/10ml | ampoule |

Figure 1.6-11. *SelectTrac-Rx Supply Browser*

Ten supplies can be displayed on a single page with each supply on one line of the form with the following information and positions:

| | |
|--------------|--------------|
| Column 1-20 | Supply Name |
| Column 22-41 | Generic Name |
| Column 43-51 | Strength |
| Column 53-59 | Form |
| Column 60-80 | Buttons |

There are 7 graphical buttons on the SelectTrac-Rx Supply Browser form, starting in column 60. Touching each button has the following effect:

1. **DISPENSE** A unit dose of the selected supply is dispensed or an Electronic Lock Cabinet drawer is opened. If the supply is in an electronic lock cabinet, the user is prompted to enter the quantity taken on a graphical keypad. If this supply requires a witness before dispensing (2nd PIN required flag), the Logon form will be displayed so that a 2nd user may logon as a witness. After the witness is verified, dispensing proceeds. If the hospital wants the remaining count verified (ELC count required flag), then the user will be prompted to enter the count remaining in the opened drawer. In either case, the supplies are automatically assigned to the selected patient.
2. **MED INFO** Displays the Medication Order for this supply (see Figure 1.6-11)
3. **UP ARROW** Returns to the previous page of patients
4. **DOWN ARROW** Advances to the next page of patients
5. **RESTOCK** Activates the inventory mode for restocking supplies
6. **HELP** Provides online instructions about using the current form
7. **FINISH** Returns to the Patient Browser form

1.9 Systems Communications

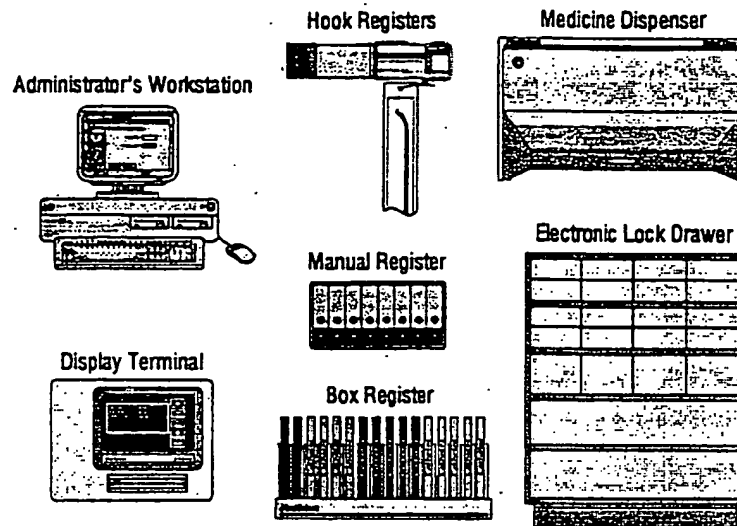


Figure 1.9-1. *The SelecTrac System*

- **Hooks to hook controllers:** The microprocessors in each Hook Register are wired in series on a ribbon cable. They are polled (asked for data) periodically by the hook controller. The polling software was developed by MedSelect. The hook microprocessors respond to the hook controller with the accumulated inventory changes at each microprocessor since the last time the controller polled it. Each hook controller can communicate with 16 hooks. Multiple hook controllers are wired in series with flat cable and RJ45 plug connectors.
- **Hook Controllers to Display Terminals:** Hook controllers communicate with display terminals through a MedSelect proprietary interface board called the IBPC (Inventory Bus Protocol Converter). The IBPC resides inside the display terminal and is connected to the display terminal's bus with a ribbon bus cable. The hook controllers are wired in parallel with a single connection directly onto the IBPC in the display terminal. It is a 4-wire connection, where 2 wires (send and receive) provide communications and two wires (live and ground) provide power to the hook controllers. Each display terminal has an IBPC connected to serial communication port 1 (COM1:) by a ribbon cable. In addition to protocol conversion, the IBPC provides error and collision detection on the inventory bus.
- **Box Registers to Display Terminals:** Box registers are wired in parallel by ribbon cable with a single connection directly onto the IBPC in the Display Terminal. Like the hook controller connection, a 4-wire connection provides communications and power to the Box Registers.

- **Manual Registers & Display Terminals:** Communicate the same way as box registers. Box registers and manual registers can be wired in parallel on the same line going to the display terminal.
- **Dispensers with Display Terminals:** Also communicate through the IBPC.
- **Display Terminals with Database Server:** Display terminals communicate with the database server via 10-base-T ethernet (RG58 thinwire, AUX thickwire & token ring are also supported). Ethernet provides the capability to have virtually unlimited numbers of display terminals communicating with the database server. Each display terminal will have a 3COM ethernet controller which is connected to the display terminal's bus by a ribbon bus cable. The ethernet board then connects to the ethernet by a 10-base-T cable to a multi-port communication hub. The communications software is LanTastic/AI by Artisoft (TCP/IP, Novell and other protocols are also supported).
- **Administrator Workstations with Database Server:** The Administrator's Workstations communicate with the Database Server using ethernet and LanTastic/AI (and other supported networks). The database is read and written to using Borland's Paradox for Windows (Run-time) software and MedSelect client-server software.
- **Admission-Discharge-Transfer (ADT) System Interface:** This interface is not yet defined and may be hospital specific. Patient admission information will be provided to the MedTrac Systems from the ADT.
- **Hospital Information System (HIS) System Interface:** This interface is not yet defined and may be hospital specific. Patient/Procedure information will be sent to the HIS when the procedure is closed.
- **MedSelect Diagnostic Interface:** This interface allows MedSelect engineers to access a customer's system remotely. This is accomplished by using internal 14.4 Kbaud modems on an analog telephone line. The software used is Symantec's PC-Anywhere for Windows which allows a MedSelect engineer to connect to the Administrator's Workstation to diagnose problems.

(x)

RELATED PROCEEDINGS APPENDIX

(none)